

Submitted to OMB/OIRA  
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("CASAA")  
December 15, 2015

## EXECUTIVE SUMMARY

FDA's proposed "deeming" of e-cigarettes under the Tobacco Control Act (TCA) would be an unmitigated disaster. E-cigarettes play the valuable role of helping smokers quit smoking or ex-smokers stay quit; they are used almost exclusively for this purpose. The proposed rule would severely limit the quality and availability of e-cigarettes and thus would encourage ex-smokers to resume smoking and discourage current smokers from quitting. In addition, it would reduce consumer welfare and wipe out most of the businesses in the sector. These harms would be literally unmitigated by *any* apparent benefits, and most of the supposed goals would actually be set back by this rule.

The TCA bans all tobacco products that were not on the market as of 2007, which means that the deeming would ban all e-cigarette products currently on the market. This is not a plan to merely assert authority in order to create real regulation; the payload is in the act of deeming itself. Real regulation includes standards that manufacturers can endeavor to meet, but there are no such standards in this case. The TCA is designed to discourage the use of products, not actually regulate them. E-cigarette manufacturers can theoretically apply to reintroduce their products after the ban. But this process would be so expensive that it is practical for only a handful of mass-production products. Given the lack of standards and FDA's history of arbitrary decisions, no manufacturer could be confident of success. A vibrant and competitive market with on the order of 100,000 products made and sold by thousands of businesses would be replaced by a hand-picked oligopoly of ten or twenty products from two or three manufacturers (probably the major tobacco companies).

There is no compelling public need for intervention in this market, let alone such a massive intervention. The maximum theoretical benefits from *any* regulation in this sector are modest, given that e-cigarettes pose low risk to consumers (and little is known about how to lower that risk further still), there is no history of major manufacturing mishaps, and the oft-claimed harms are either mythical or of modest magnitude. FDA has not produced even a *prima facie* case that the deeming ban and other rules they plan will further any of their goals, let alone quantified the supposed benefits and compared them to the enormous costs. Our analysis of real effects of this

rule shows that there is no reason to believe any stated or implicit goal will be advanced, and it will clearly set back most of them.

A major reason for some of the failures is that the rule would create alternative e-cigarette markets – black markets, self-importing, do-it-yourself manufacture, and a legal shadow market for some components – that would easily outcompete the government-sponsored oligopoly on variety, quality, and price. These markets would be inferior to the *status quo* legal market in almost every way, including cost, purity, and safety. Few of these alternative suppliers would obey any regulation or pay taxes. FDA was explicitly warned that this action would create these alternative markets, but has failed to seriously acknowledge this, let alone assess the repercussions.

Most of the stated and implied goals of this regulation would not be advanced substantially if the ban were effective and only the legal products existed. The alternative markets would eliminate even the modest benefits that might result under that scenario. The real results would include lower average product purity and safety, increased risk of accidents, greater access for minors, and foreclosure of genuinely useful regulation in the future. The rule fails a cost-benefit test by default, because there are no apparent benefits; FDA has made *no* case that their action would produce them.

FDA has never attempted to assess the real results of this rule or estimate the costs. We have. A survey of over 20,000 of our members who use e-cigarettes, which we believe is fairly representative of roughly a million e-cigarette enthusiasts, indicates that 90% of them plan to keep using the products they currently use, via one or more alternative markets, after FDA bans legal sale of their preferred products. Yet at the same time, 20% of them indicated they expected to resume smoking (or smoke more than they already do for those who still smoke some) under the FDA ban. Even the most charitable assumptions put the health cost from that additional smoking in the order of *100 times greater* than any health benefits that might result, to say nothing of other welfare losses.

The millions of other Americans who use e-cigarettes but are less committed to them would undoubtedly return to smoking at a higher rate, and the millions of current smokers who might have been persuaded to switch to e-cigarettes will be much less inclined to do so. These individuals would have less access to information and alternative sources of supply than the enthusiasts. This will mean a lot more people who smoke until they die from it. Almost all respondents to our survey (99%) said they believe they would still be smoking now had they not discovered e-cigarettes.

FDA has attempted to justify the enormous harm they would cause to the target audience for e-cigarettes – adult smokers and would-be smokers – by implying that there would be benefits

from reducing underage use. But the reality is that even the potential benefits are, at best, modest and this particular rule would not produce them.

In addition to the massive net costs and FDA's failure to make a case that there are any benefits, there are various serious problems that independently make this unacceptably bad public policy. This is a massive intervention -- the second-most impactful domestic policy action in recent memory -- being treated as a mere technical adjustment. Such social interventions inevitably produce negative and secondary consequences, and yet FDA has failed to seriously assess these. The rule would create a legal and enforcement nightmare and health disparities, and it would delegitimize federal regulatory policy. It would create a government-sponsored oligopoly and invite crony capitalism.

The most difficult challenge in analyzing and understanding this proposal is overcoming the natural tendency to assume that nothing can ever really be this bad -- that you must be overlooking something. In this case, it really is as bad as that: No compelling public need, modest maximum theoretical benefits, no apparent actual benefits, enormous costs in terms of the agency's own goals, and more enormous costs in other areas. One need not dispute FDA's own analyses to reach those conclusions because FDA simply has not produced any meaningful analyses.

There are no details of this proposed rule that could be changed to substantially reduce the huge net harm it causes, let alone to make it beneficial. The only way to achieve that would be to delay its implementation until such a time that rational and beneficial regulation can be created.

## Overview

This report is submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA). CASAA is a 501(c)(4) nonprofit public health and education NGO and is the leading representative of consumers who use or might in the future use smoke-free tobacco/nicotine products. It is a U.S. membership organization with over 120,000 members. CASAA is not an industry group and does not represent the interests of industry.

This report is intended to address FDA's proposed deeming of e-cigarettes as being under their jurisdiction as a "tobacco product" under the Family Smoking Prevention and Tobacco Control Act (TCA). We are not addressing the deeming of certain combustible tobacco products that is included in the same proposed rule.

The deeming rule is widely interpreted among officials and members of the public who are vaguely familiar with the proposal as a mere assertion of authority that allows regulations to be created. The reality is that due to the details of the TCA, compounded by FDA's procedures for regulating tobacco products, the deeming itself is actually a massive policy intervention. It is an unstated ban of all e-cigarette products currently on the market, possibly followed by granting permits for a few relatively low-quality products to be sold after that. In terms of its impact on people's lives and commerce, it would arguably be the second-most impactful domestic policy of the decade. It needs to be evaluated with this in mind.

The most important background science is very simple: E-cigarettes are a low-risk alternative to smoking. They are used almost exclusively as a way to quit smoking, remain free of cigarettes, or significantly reduce cigarette consumption. In fact, e-cigarettes appear to have contributed more to reducing smoking than anything since the initial education about the risks launched two generations ago. (The latter caused an enormous reduction in smoking but the effects have largely plateaued, suggesting the need for alternative strategies.)

More than a million Americans have quit smoking thanks to e-cigarettes, and there is the potential for millions more. The variety and widespread availability of e-cigarettes contribute to that effectiveness and continue to provide inroads to convincing more smokers to quit. To the extent that there is any health risk from using e-cigarettes (and there is no affirmative evidence that there is), it is undoubtedly a tiny fraction of the risk from smoking. Typical estimates put its health impacts in the range of 1/100th of that from smoking, down in the range of everyday hazards like eating french fries or commuting. Thus, e-cigarettes have contributed enormously to people's welfare and the health of the population, as well as creating a vibrant new industry.

Several further details about the role of e-cigarettes in the world are also important: Open-system products -- those that allow consumers to combine hardware components and, most important, refill the devices with their choice of liquids (which come in a variety of flavors and nicotine

strengths) appear to be much more effective at promoting smoking cessation. All of these products would be banned under the rule, with almost no chance of any being allowed on the legal market.

A small oligopoly of closed-system products -- often called “cigalikes” because they mimic the form factor of cigarettes and usually flavored to roughly imitate cigarettes -- will probably receive FDA approval. These products can serve as a familiar introduction to e-cigarettes for smokers with low entry costs. However, many smokers find they are not inclined to give up smoking until they discover the advantages of open systems, including better vapor and nicotine delivery, longer battery life, and far lower long-run costs. Perhaps most important, the variety of appealing flavors give smokers an active reason to appreciate the low-risk alternative rather than grudgingly accepting it as a safer but inferior substitute. In addition, the specialty market that has sprung up for open systems provides smokers with important knowledge about the options and their advantages compared to smoking.

The proposed rule imposes a draconian intervention in the vibrant and beneficial free market for e-cigarettes that could only be justified if that rule were to eliminate a dire harm to consumers. But there is no such harm. In fact, the rule will eliminate much of the huge net benefit that e-cigarettes have contributed and would contribute in the future. Some former smokers will return to smoking and many smokers who would have quit will be denied that opportunity. E-cigarette users will be denied legal access to something that, for hundreds of thousands of them, is the most important thing in their lives after friends, family, and basic sustenance. Yet there is no reason to believe that the rule offers *any* benefits to offset that harm.

The enormous impact of the proposed rule is driven largely by the TCA provision that any FDA-regulated tobacco product that was not on the market before a certain date is banned unless the manufacturer obtains FDA approval to introduce it as a new product. This “grandfather date” written into the TCA is February 15, 2007. While the cigarettes and smokeless tobacco that FDA already regulates are static technologies, and thus many products were grandfathered, none of the current e-cigarette products on the market existed in 2007. (Nothing all that similar to any current products had even been developed yet.) Thus, *the mere implementation of this deemed is a ban on all existing e-cigarette products.*

It is crucial to keep in mind that this is not regulation in the practical sense of the word. Real product regulation has standards for characteristics, performance, or manufacture of the products that a manufacturer could meet. It involves details that can be discussed and improved. There are no such details in the present case. All existing e-cigarette products would be banned, without manufacturers being offered the opportunity to meet regulatory standards.

The theoretical opportunity to reintroduce those products after the ban is immaterial for all but a handful of products, since the cost of submitting a serious application alone is prohibitive. This is

a market that includes on the order of 100,000 SKUs, the overwhelming majority of which have annual sales of less than \$10,000. The cost of a serious application is likely to be seven or even eight figures *per product* due to the research that appears to be required and the application cost itself. Thus, the application process is precluded for 99.9% of the products on the market, and practical only for a handful of mass-production products -- all of which are cigalike products made by the major tobacco companies and a few of the largest specialty manufacturers -- even if approval of the application were guaranteed (which is clearly not the case). All other products are permanently banned as a result of paperwork burden.

Moreover, the FDA processes for approving new products and changes to existing products are effectively designed and implemented to make approval unlikely. Whatever one might think about such intentional gumming up of the market for combustible tobacco products, it is clearly inappropriate to impose on low-risk alternatives to cigarettes. FDA has issued only the vaguest guidance for what an application should contain and even less for what product characteristics would be sufficient to garner approval. Again, this is not regulation in any normal sense of the word wherein manufacturers are given standards and are required to show that they are meeting them. What appears to be a draft FDA guidance document for approval of "new" e-cigarettes (which would apply even if they were not new) has been leaked, and it contains basically the same requirements and vagueness as all previous application guidance documents. In any case, nothing has been produced by FDA that suggests the procedure will change substantively. FDA's decisions involve almost no transparency, with very little or no information about the reasons for the decisions made publicly available -- and, indeed, relatively little to the applicant itself -- so future applicants who observe the history of the process learn nothing (other than that their applications are likely to be rejected for unforeseeable reasons).

FDA decisions about tobacco product applications to date have been arbitrary and opaque, as would be expected under the completely arbitrary process conducted without transparency. Effectively, each decision is a free-standing policy decision rather than an enforcement of a regulatory standard. Applicants have no basis for confidence that *any* application will be accepted. Indeed, the guidance documents FDA has prepared for applications for the products they currently regulate call for providing particular evidence about the effects of approving the application that is literally impossible to provide, offering an easy excuse for refusing any application. There are reasons to believe that FDA will approve a handful of cigalikes for political reasons. Once approved, however, these products will be largely frozen since any change to them would require yet another approval process. While this has limited impact on traditional tobacco products, e-cigarette technology is improving on a month-to-month basis, and the approved products would already be obsolete the day approval was granted.

While FDA rhetoric implies that they support tobacco harm reduction, favoring low-risk products over cigarettes, their past behavior regarding smokeless tobacco products clearly shows this is not the case. Thus there is no reason to believe that their obstructionist approach will not

be extended to e-cigarettes. They have offered nothing that can be considered an assurance to the contrary.

FDA does not present even a *prima facie* case that there are *any* benefits from their regulation. FDA seeks to impose a rule that would, even absent any further restrictions, replace a vibrant diverse market that provides enormous net benefits to welfare and health with a tiny market of relatively low-quality -- and technologically outmoded -- products. Yet their justifications for this take the form entirely of vague references to factors that (in their view) *could* be better. They offer no analysis or concrete proposals that suggest these *would* be better under their regime. They act as if this deeming were merely an assertion of authority that would be followed by concrete substantive interventions. But the payload of the deeming itself is a massive intervention, and thus it must be justified as such.

In addition, the intervention would not actually cause the banned products to disappear. FDA has made no serious attempt to assess the real effects of this rule. While they imply that under this rule, only FDA-regulated e-cigarettes would exist (which would be a terribly harmful outcome in itself), the reality is that the ban of most products on the market would actually create a huge alternative supply for the desired products -- a combination of black markets, self-importing, and do-it-yourself manufacture. This supply chain would be inferior to the current and ever-improving supply of high-quality products in almost every way. The quality of the products people use would be decreased and the potential for harmful mishaps would be dramatically increased. All potential for genuinely beneficial real regulation would be lost.

There can be no serious doubt that these alternative supply chains would emerge by the time the blanket ban took effect following whatever grace period. Indeed, if FDA acts to dramatically reduce the quality of e-cigarettes before the grace period ended -- in particular if they moved to restrict the variety of flavors available, as is rumored to be included in the proposed rule -- the alternative markets would come into being even before that. FDA has offered no acknowledgment of how inevitable this outcome is.

Once the real consequences of the rule are considered, in particular the creation of alternative markets, it is possible to provide the analysis of this rule achieving its stated and implicit aims, the policy analysis FDA has failed to even attempt. Even a simple analysis shows that the rule will be actually detrimental in terms of every stated or implicit benefit. Public health will be harmed. Fewer smokers will switch to this low-risk alternative. The many consumers who acquire products through alternative channels will consume lower-quality products -- in particular, be subjected to more risk -- than they otherwise would have. Risks from accidental exposures will increase dramatically. No beneficial regulation will be possible at the federal or state level. Access to e-cigarettes by minors will almost certainly increase rather than decrease.

That last point warrants particular attention because much of the ostensible justification for this rule focuses on underage use of e-cigarettes. This phenomenon has been grossly overstated by proponents of regulation, mainly by conflating ever trying one puff from an e-cigarette with being a “user” of the products. Moreover, it is not clear that even the modest level of real use results in a net harm given that, as with adults, e-cigarettes appear to be a substitute for smoking or other risky behavior. In addition, the common claim that e-cigarette use by teenagers is a “gateway” to smoking is completely unsubstantiated and, indeed, is an absurd claim when considered closely. But these observations are largely moot because the market for e-cigarettes that exists following the ban will undoubtedly be *more* accessible to teenagers -- and probably more appealing -- than the legal free market that currently exists.

The proposed rule violates numerous norms of proper public policymaking, norms that exist for very good reasons. In addition to the costs clearly exceeding the benefits, FDA fails to provide any serious policy analysis that there will be any benefits and likewise fails to seriously consider the actual consequences. There are additional serious problems: The policy is misrepresented; it is an absolutely massive intervention in the free market and the lives of millions of people, portrayed as if it were a minor technical rule. It would replace a vibrant free market with an oligopoly. This policy would create a regulatory and enforcement nightmare and encourage flouting the laws of the land. It would facilitate crony capitalism and create health disparities.

In summary, this policy would impose enormous costs on consumers, in particular damaging their health. It would discourage smoking cessation. It would replace a safe and productive legal market with an inferior black market. There is no reason to believe that it would further any of its aims, and ample reason to believe that it would set them back. This rule fails a cost-benefit test even if only the supposed benefits are considered, ignoring the enormous costs.

There are proposals for modifications of the rule that would reduce its net harms, but nothing short of disallowing this deeming, pending the creation of new enabling legislation, could actually eliminate the enormous net harm it will cause. In political fights over public policy, a typical rule of thumb is that nothing is as bad (or good) as opponents (or proponents) say it is, and that the optimum lies somewhere in between. It is crucial to understand that this is one of those exceptions where there is literally no upside to the proposal.

### **Properly interpreting what is being proposed**

It is possible to envision genuinely beneficial regulation of e-cigarettes by the federal government or other authorities. Indeed, FDA’s proposed deeming of e-cigarettes is widely interpreted among officials and members of the public who are vaguely familiar with the proposal as a mere assertion of authority that allows beneficial regulations to be created. The reality is that due to the details of the TCA, compounded by FDA’s procedures for regulating tobacco products, the deeming itself is actually a massive policy intervention that largely

forecloses the possibility of genuinely beneficial regulation. It is effectively a blanket ban of the products that will replace the high-quality legal market that currently exists with unregulatable alternative markets (discussed below). It needs to be evaluated with this in mind.

Three basic facts define any legitimate discussion of the proposed FDA rule:

1. The proposed rule is a *de facto* ban on an entire product category, and not regulation in any normal sense of the word. FDA has failed to analyze the rule in the context of the real impacts, analyze the real impacts, or even to clearly state that this is what the rule would do.
2. The potential (gross) benefits of this rule are extremely low. There is nothing close to a compelling public need for this rule. FDA has failed to provide convincing justification -- either scientific evidence or policy analysis -- that there is a problem that the proposed rule could solve.
3. The immediate effects of the rule create enormous costs, and the secondary effects will probably be greater still. FDA has failed to conduct anything that could be considered a remotely legitimate cost-benefit analysis.

#### A ban, not real regulation

The most important thing to understand about this proposed rule is that it is not actually a regulation in any normal sense of the word. It does not contain manufacturing, product, or performance standards that producers can endeavor to meet. It does not contain technical details that might be the subject of debate or compromise. It does not impose rules designed to fix problems related to product quality, public health and safety, or other legitimate regulatory concerns. The real implications of this rule, quite contrary to what FDA has implied it will do, are driven by the following three characteristics. For all practical purposes these are the only factors that really matter for the proposed deemинг; details of any subsequent rulemaking under the deemинг (short of the massive and unlikely alteration of current FDA procedures addressed below) will have relatively trivial impact.

a) Almost all the impact of the regulation comes merely from the act of deemинг. The deemинг would subject e-cigarettes to the same bans and approvals processes that exist for cigarettes and smokeless tobacco. There are no details of the proposed rule itself that offer any room for consequential amendments or compromise on this point. Normal regulations involve room for compromise over quantities or other details, but there are no such details in this case.

b) The details of the TCA include a provision that any products not on the market as of February 15, 2007 must go through an approval process as a new product. Since there is currently no e-cigarette product sufficiently similar to any product that existed on that grandfather date, this

means that the “regulation” is a ban of all existing e-cigarette products, with the theoretical option that they can secure approval as a “new” product under the premarket tobacco application (PMTA) process. This is fundamentally different from the imposition of a real regulatory standard that manufacturers could bring their products into compliance with. There is no such option for compliance. (It has been suggested that this date be changed for e-cigarettes, though FDA’s position is that it is immutable; in any case, merely changing the grandfather date would provide very limited reduction in the net harms caused by this rule, as noted below.)

c) The FDA approval processes for tobacco products is, by design and as demonstrated in practice, arbitrary and primarily intended to prevent new products from being approved. The approval processes -- for new products (PMTA), to be able to make health-related claims about products (the “modified risk tobacco product” (MRTP) process), and even to be able to make minor changes in existing products (the “substantial equivalence” (SE) process) -- are extremely expensive and onerous. Applications are usually rejected or denied by FDA, often for reasons that the applicant had no way of anticipating. Whatever one might think of imposing such a process to impede innovations in highly risky combustible tobacco products, the function of these processes must be seen for what they are: creeping prohibition-by-paperwork under the guise of regulation. FDA provides no standards for any of these processes, such that if a product meets them, the manufacturer can expect the application will be approved. Thus, every application is not just expensive, but highly uncertain, and decisions are ultimately arbitrary.

While there are not clear standards for what an application should contain, the FDA “guidance” documents for applications for products they currently regulate calls for information similar to that required for pharmaceutical product applications. This alone makes the process extremely expensive, to say nothing of being a very bad fit for a product that is freely chosen by consumers based on many characteristics, not merely because of medicinal efficacy. This misfit presumably contributes to there being no actual requirements for what a manufacturer must demonstrate in an application, as there are with pharmaceuticals. This makes the expensive process also utterly uncertain. It thus can only be considered feasible for a product that is expected to generate tens of millions of dollars in revenue per SKU. It is not conceivable that there will be serious new product applications for more than about 25 e-cigarette products (these are FDA’s own estimates, which seem plausible). Probably only the major tobacco companies could navigate this regulatory maze, and even some in that sector have told us that the burden appears to be insurmountable even for them. Therefore, the net effect of the proposed regulations will be to permanently ban on the order of 99.99% of the roughly 100,000 e-cigarette products on the market today.

These three observations mean that the proposed deemings contains no room for reasonable compromise. Regulations are normally assessed, debated, and compromised upon based on their details. But these three factors mean that a mere one-sentence version of the proposed rule (“E-

cigarettes are tobacco products and subject to FDA tobacco product regulation.”) would contain basically all the payload.

There is no compelling public need for the proposed regulations and the maximum theoretical benefit is very small

Below, after assessing the real effects of this rule, we analyze the impact on goals of the regulation and show it will actually have net negative effects on them. But it is not even the case that *some* FDA regulation in this sector could *theoretically* attain major benefits that meet the “compelling public need” standard. This is true even if we do not consider the enormous costs or the inevitable failure to further the goals. (All these points are presented in more detail below.)

There is little room to make the products safer, and in any case, no knowledge about how to do so that is not already being implemented in the free market. E-cigarette use poses very low risk, down in the range of everyday lifestyle choice, and not at all similar to the risks from smoking (even setting aside the fact that almost all e-cigarette use is as a substitute for cigarettes). Thus the potential for *any* regulation to reduce the health risks to users is speculative and, at most, very small. The potential for reducing mishaps is similarly low. There are no known cases of a major manufacturing problem that had the potential to seriously harm consumers. There is concern about poisonings from accidental exposures, though the actual number of these is quite small and dropping.<sup>1</sup>

There is no evidence that consumers are misinformed about e-cigarettes in ways that could be improved by regulation. To the extent that there is misinformation, it is overwhelmingly in the direction of thinking the health risks from e-cigarettes are similar to that from smoking, or otherwise overestimating the risk.

There is much talk about using regulation to prevent minors from using e-cigarettes. But the claims about the magnitude of such use are greatly exaggerated, and it is far from clear that it actually is causing net harm. These points are addressed in detail below in the context of what the regulation would really do. But FDA has not even suggested how the regulation would lower such use, nor argued that such impacts would be beneficial on net, which is genuinely ambiguous. In any case, any resulting material benefits would be modest.

All this sets aside the fact that the proposed rule would actually *set back* all of these goals rather than advancing them, and that *real* regulation might advance them, but would be effectively foreclosed by this rule. The point here is that even if every supposed benefit of FDA regulation

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<sup>1</sup>There has even been an absolute decrease, without normalizing for quantity consumed, as reported by Kevin Chatham-Stephens of CDC to FDA:  
<http://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM454403.pdf>, p.520;  
<https://www.youtube.com/watch?v=rQSRG6hmh-c>, at and around 2:02:00.

were achieved, the actual beneficial effects would be extremely modest. This alone makes the proposed draconian intervention in the market bad policy.

Moreover, FDA has never offered even a *prima facie* case for how this particular rule would actually bring about any of the potential benefits, let alone quantified the resulting benefits. They simply refer to potential benefits and imply it is self-evident that this rule would further them; that is far from the case.

#### The costs of the rule would be enormous

The rule would cause a major loss of consumer welfare and cause an increase in smoking (and costs that result from that), while simultaneously driving a large and growing industry into the black market and overseas.

This rule would immediately eliminate an entire sector of small and medium businesses from the country. Some manufacturers would relocate overseas, but many would simply close. In all cases, their contribution to the U.S. economy would be lost. The specialty stores that are instrumental in educating smokers about their options for switching to this low-risk alternative would simply be eliminated.

If the rule then really achieved what is intended -- actually eliminating all the banned products along with the businesses that supply them -- it would have huge negative impacts on consumer health and welfare. There would probably be a few e-cigarette products left on the market (though even this is far from certain), but they would inevitably be an extremely limited variety of closed-system “cigalike” products. Most experienced e-cigarette users strongly prefer open systems (e-cigarettes with modular hardware components which the consumer refills with separately purchased liquid) because they deliver more effectively, offer a much wider variety of flavors and nicotine strengths, have better batteries, and are cheaper in the long run. Moreover, the technology for the FDA-approved products would be largely frozen, ending the continuous quality improvement that currently exists in this technology.

Current consumers who switched to the inferior products would immediately experience a substantial welfare loss with no offsetting benefit. Moreover, because the cigalikes are not an adequate substitute for smoking for many consumers, many of them would instead switch back to cigarettes, lowering their welfare and harming their health. Many smokers who would have switched to e-cigarettes will continue to smoke. (All points here are further detailed below.)

The reality is, however, that the legal market would be replaced by alternative black/grey/shadow markets. This would reduce the harms caused by the rule, but it would also eliminate all the supposed benefits. In fact, the alternative markets would be inferior for consumers and create other costs for society as a whole. However, since only consumers who are

already enthusiastic about e-cigarettes would be likely to take advantage of the alternative markets, few current smokers will have the opportunity to quit using e-cigarettes.

It is really that bad

Executive Order 12866 -- and tenets of good public policy more generally -- requires that agencies consider the costs and benefits of a rule, and quantify them to the extent possible. The agency should then choose the option, which might be imposing no new rule at all, that maximizes the net benefits. But in this case, not only has FDA failed to quantify any benefits, FDA has not even presented a *prima facie* case that their proposed intervention will bring about the goals that are given to justify it. Similarly, FDA has not only failed to quantify the costs, but has not even seriously tried to identify those costs.

When the analysis of costs and benefits is laid out, as it is below, it becomes apparent the rule would impose enormous costs without creating *any* apparent benefits. If the rule were to do what FDA implies it would, eliminating the market for unapproved products, the benefits would be modest and the health, welfare, and commercial costs would all be enormous. If we instead consider what will actually happen, the benefits are nil and the net harm to welfare and health are reduced, but still enormous. FDA has never seriously assessed the costs and benefits, let alone made a case that the benefits justify the costs. The cost-benefit analysis is actually quite simple, and completely one-sided.

When considering the ramifications of this proposed rule, it is necessary to try to suspend the common biases of assuming “nothing is ever as bad as that” and “there is room for reasonable compromise; something in the middle of the distribution of what is being asked for is best.” Observers who are not immersed in a topic typically hesitate to believe that a common claim is utterly groundless or a proposed policy has no apparent upside. In most cases, they would be right. But when it comes to the Tobacco Wars (and other wars on drugs and other health-affecting behavior choices), where unstated moral agendas are hidden behind technical claims that are often utterly false, these normally reasonable conservative assumptions can mislead.

In terms of real impact on people’s lives, there is a good case to be made that this is the second most important domestic policy action of the decade. It will cause a major change in the lives of more people than any domestic policy in recent memory other than the Affordable Care Act. It is of enormously greater importance to them than any product regulation, environmental regulation, infrastructure policy, or even change in their tax rate. It will attempt to take away something from a few million people that most of them consider one of the most important things in the world, often *the* most important after basic sustenance, family, and friends. Yet it is being put forward without serious analysis as if it were a mere technical adjustment of jurisdiction, and with the paltry consideration and analysis that might be acceptable if that were the case.

### No potential for substantial benefit to consumers, but inevitable high costs

Many proponents of this rule traffic in disinformation about the basic science about e-cigarettes. While FDA itself is not so guilty of out-and-out false claims about the health science, they do rely heavily on innuendo that exaggerates various risks and uncertainties in order to imply that the potential benefits of their action are greater than they really are.

### Low risk to users

Any health risk from using e-cigarettes is speculative, and all the evidence shows it would be modest, somewhere down in the range of everyday hazards, and far, far less hazardous than smoking.

E-cigarettes are generally estimated to be in the order of 99% less harmful than smoking, and there is actually no affirmative evidence there is any health risk except for people with specific contraindications for exposure to nicotine or other ingredients. This estimate is based on (1) the epidemiology that shows that any risk from smoke-free nicotine in the form of snus (moist snuff) is too small to measure and thus is on this order. Notably, this is the same evidence that FDA used to help conclude the nicotine products it regulates (e.g., nicotine gum and patches) will not pose a measurable risk if used in perpetuity<sup>2</sup>, and (2) no reported chemical analysis of e-cigarettes has found any exposure that would substantially increase the risk compared to snus.<sup>3</sup> Appropriate regulation to make any of those minor hazards less hazardous can be justified, of course, but a near ban of an entire product category based on such small and speculative risks is clearly inappropriate. That would be the case even if one were to ignore the huge net health benefits caused by e-cigarette use.

Given that nicotine causes a transitory increase in blood pressure and heart rate, we cannot rule out that it causes an increase that is too small to detect for the risk of cardiovascular disease. On the other hand, caffeine has the same effects, but the current assessment is that coffee consumption is health-beneficial on net. In any case, we have overwhelming evidence that the net health effects of nicotine are very close to zero. Other chemicals delivered by e-cigarettes introduce other possible modest health hazards. However, there is strong evidence that the risks remain slight. For the chemicals that have been detected in e-cigarette vapor, a simple comparison to levels of exposure that are actually believed to be hazardous shows that there is no reason for concern.<sup>4</sup> Alarmist claims about delivery of these chemicals almost invariably ignore the fact that the doses are inconsequential.

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<sup>2</sup> <http://www.fda.gov/forconsumers/consumerupdates/ucm345087.htm>

<sup>3</sup> For an assessment of how to conduct such analysis and a review of the then-available data to date, see Burstyn, "Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks," <http://www.biomedcentral.com/1471-2458/14/18>.

<sup>4</sup> *Op cit*

It is also possible that long-term lung involvement creates unknown hazards, even from the generally benign carrier chemicals in e-cigarettes. But again, there is every reason to believe any such health risks are minimal given that there is no evidence from occupational exposure (the common method for evaluating the effects of chemical exposures, since they tend to be highest) to suggest a problem. There have not been any credible reports of serious acute health effects after nearly a decade of widespread use, making clear that any risk of such effects is minuscule.

Thus the room for improvement, in terms of health risk, is minimal. *Elimination* of whatever modest health risk e-cigarettes might inherently cause would only occur if e-cigarette use were eliminated entirely. Since neither the proposed rule nor any conceivable intervention would do that, that possibility is moot. There is speculation that some flavoring agents or product configurations (e.g., those that facilitate higher temperatures) pose hazards -- too small to detect, but not zero -- though these claims have never been substantiated. Real regulation could theoretically reduce these hazards, though the maximum possible benefit remains minor, but there is no reason to believe that FDA could actually bring about such improvements any faster than the free market will. In any case, the ban is not this kind of regulation, and the unfettered alternative (black/grey/shadow) markets would undoubtedly *increase* these hazard compared to allowing the legal market to continue to evolve.

FDA does not actually contend that there is any substantial health risk from e-cigarettes, though they tend to imply that the risk is greater than the evidence suggests. They do claim that the uncertainty about the risk is much greater than it really is, which is an easy and common rhetorical tactic in many contexts since it requires merely ignoring the evidence or claiming it is imperfect and therefore completely uninformative. If FDA is truly as uncertain about the risks as they suggest, there is clearly no reason to believe that they are in the position to bring about any substantial improvements to the products. If the proposed rule were merely the technical assertion of authority that it is portrayed to be, it would be acceptable for FDA to take the action from a position of ignorance, planning to gain knowledge before imposing substantive rules. But because this is a substantive intervention, they are obliged to demonstrate how it brings about a substantive improvement, which they have not done.

In summary, reduction in possible hazards to consumers cannot realistically be counted among the potential benefits of the rule.

#### Used almost exclusively for smoking cessation

On the consumers' health cost side of the ledger, dwarfing even the maximum theoretical possible benefits, is that restrictions on e-cigarettes will cause more smoking. Approximately all

actual users<sup>5</sup> of e-cigarette used them to quit smoking and/or use them to avoid the temptation to go back to smoking.<sup>6</sup>

Encouraging people to quit or avoid smoking via basic factual education about the health risks has been very successful over the course of a half-century, but its effects slowed far short of eliminating smoking. Despite literally thousands of other interventions, none of them have made much difference (the only such intervention with genuinely measurable impacts is high taxes, and those are as high as they can practically be). But the one intervention that has proven to make a huge difference is tobacco harm reduction (THR), substitution of low-risk alternatives. Sweden with the substitution of snus is the huge success story, and Norway is more recently trending similarly. Unfortunately, THR using smokeless tobacco has largely failed in the USA (thanks mainly to a successful disinformation campaign that misled consumers into believing smokeless tobacco poses substantial health risk), but e-cigarettes have already proven very successful.

Though the available data is limited, it appears that more than a million Americans have quit smoking entirely thanks to e-cigarettes and far more have substantially reduced their smoking by substituting e-cigarettes. The rate of switching seems to still be accelerating rather than slowing, and thus there is every reason to believe that maintaining the current innovative, diverse free market in e-cigarettes will cause millions more smokers to quit smoking or smoke substantially less than they otherwise would have.

Most ex-smokers who quit by switching to e-cigarettes are fairly sure they would still be smoking if they had not had the option to switch, and there is no reason to doubt their self-assessment. In our recent survey of over 20,000 CASAA members, 99% reported this. (CASAA membership is limited to adults and is about 99% American, and those members who use e-cigarettes are reasonably representative of the roughly one million e-cigarette enthusiasts in the USA; the survey methodology is described in the appendix.) Many of those who switch to e-cigarettes have tried many or all of the officially recommended methods of smoking cessation and found them ineffective. CASAA has collected over 7,600 testimonials (and counting) of people who quit smoking thanks to switching to a smoke-free alternative, mostly e-cigarettes, which is available at <http://testimonials.casaa.org/> and a copy of the testimonials is attached to the delivered version of this report. These success stories, many of which are awash in gratitude for this opportunity to switch away from smoking, *by themselves* represent enormous benefits from e-cigarettes, let alone when extrapolated to the rest of the population.

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<sup>5</sup> This phrase is to distinguish people who really make a practice of using e-cigarettes from the many others who have merely tried them. In many misleading statements, the latter are mischaracterized as users or “ever users.” Trying an e-cigarette, given its trivial risk, is a perfectly rational behavior that can be motivated by mere curiosity. It is actually surprising how many adults have never tried even one puff of an e-cigarette. The number of non-users who have merely tried an e-cigarette will obviously continue to increase, but it is of no consequence whatsoever.

<sup>6</sup> This common knowledge is confirmed by our survey, described below, and all other research on e-cigarettes users that we are aware of (e.g., <http://www.mdpi.com/1660-4601/11/4/4356>).

One particular observation that is apparent from these testimonials, the existing surveys of dedicated vapers, and general communications among consumers is that many smokers find they are not inclined to give up smoking until they discover the advantages of open systems. These include better vapor and nicotine delivery, longer battery life, and far lower long-run costs. Perhaps most important, the variety of appealing flavors give smokers an active reason to appreciate the low-risk alternative rather than grudgingly accepting it as a safer but inferior substitute. In our survey, about 2/3 credit the variety of flavors with helping them quit smoking (for those who quit) or keeping them on the path to eventual quitting (for those who still smoke). This contrasts with only 4% who indicated that flavors were not really important to them.

There is a persistent mythology, driven only by fact-free propaganda, that interesting flavors are designed to attract children to e-cigarettes. As noted below, there is actually no evidence these flavors increase underage use at all. But anyone at all familiar with “vaping” culture knows that these flavors are much beloved by adult ex-smokers, who typically attribute much of their confidence they will never smoke again to the availability of those flavors. In our survey, 78% of respondents indicated that they use sweet flavors (fruit, candy, pastry, or soda) most or all of the time, with only 7% using them rarely or never. This compares to 11% who indicated that they use tobacco/menthol flavors most or all the time, and 64% who use those flavors rarely or never. Indeed, 31% specifically indicated that they started out with tobacco/menthol flavors but switched entirely or almost entirely to other flavors. All previous research about users of open-system e-cigarettes has produced similar patterns. Claims that interesting flavors are targeted at children rather than adults are flatly contrary to an enormous body of easily-accessible evidence.

In addition, the specialty market that has developed around open systems provides smokers with important knowledge about the options and their advantages compared to smoking. Thus the exceptions to the blanket ban will be the products that are least effective for smoking cessation. In our survey, less than 5% indicated a willingness to use the available cigalikes, even sometimes, that would presumably remain on the legal market under the proposed rule.

Under the rule, many current e-cigarette users would return to smoking or increase how much they smoke. FDA has all but ignored this very direct cost of their rule; they have no idea how much their action will interfere with smoking cessation, and have not attempted to assess it. Indeed no one, to our knowledge, has offered a quantitative estimate, though many have pointed out that there can be no doubt that this makes the net population health costs of the ban negative given how much more hazardous smoking is than e-cigarette use.

We are able to contribute a bit of knowledge that could be used for such quantification: Respondents to our member survey are among the most dedicated to vaping among all current e-cigarette users. When asked what they would do in the event of (i) a total ban, (ii) a ban on all but a few cigalikes, or (iii) merely a ban on flavors other than tobacco/menthol, about 90% of

them indicated they would turn to alternative (black/grey/shadow) markets to try to keep using their preferred e-cigarette products, as discussed below. But in spite of most having that plan, many indicated they would resume smoking or increase how much they currently smoke: 21% of respondents under each of the first two scenarios and 14% under the third scenario. Only about 5% said they would quit using all tobacco/nicotine products. Thus, even in this subpopulation, the negative health consequences would be in the order *100 times greater* than the health benefits, even if we make the extremely pessimistic assumption that e-cigarettes are 1/20th as harmful as smoking and the extremely optimistic assumption that alternative market products will pose no higher risk than current legal products.

The percentage resuming smoking among the large majority of e-cigarette users who are not so dedicated to e-cigarettes as to join CASAA would undoubtedly be higher. More of them might quit entirely, for the same reason, but since the health effects of smoking dwarf the effects of e-cigarette use, the net health effects in this subpopulation will certainly be even worse than they are for the CASAA subpopulation. Those who use both products will be particularly likely to retreat into just smoking and not complete their potential transition. The much larger subpopulation of current smokers who might someday be persuaded to switch would become even less likely to do so under the severely restricted market.

There is simply no possible level of optimism when assessing the proposed rule that does not result in the health costs overwhelming all the conceivable benefits. Denying smokers and would-be smokers the choice of high-quality low-risk alternatives to smoking is completely counterproductive for any public health goal of the policy.

FDA and proponents of this rule frequently write as if it is being implemented in a country where combustible cigarettes do not exist, or one in which smoking is spontaneously disappearing (clearly not the case) or regulatory actions will force people to quit smoking (there is no hint of such actions on the horizon, nor even a plausible suggestion for how that might be done). E-cigarette use is presented as if it were an isolated phenomenon. Though occasionally a proponent of the proposal pays lip service to the real role of e-cigarettes, they clearly do not take it seriously. While the proposed rule would not be as harmful as e-cigarettes disappearing entirely -- not least because it will be flouted by those who are already dedicated vapers -- it will discourage further switching by making e-cigarettes less appealing and less available, and will cause some former smokers to simply switch back. It is difficult to try to quantify how much more smoking the rule would cause, but the difficulty does not excuse FDA from their responsibilities under Executive Order 12866 to conduct such an analysis. Any such analysis would show the negative effects of this rule would dwarf the maximum conceivable benefits that could even theoretically result from regulation.

Claims about e-cigarettes promoting or exacerbating smoking are unsupported

Given that the health effects of e-cigarettes are dominated by their effects on smoking, the only possible way that the free and diverse market in e-cigarettes could cause harm that makes any substantial dent in the benefits it creates is if somehow it causes smoking. This, of course, is equivalent to saying this is the only conceivable pathway for draconian restrictions on that market to create benefits that offset much of the costs that the restrictions create. But there is literally no evidence that supports this contention.

Many proponents of the proposed rule argue that since most e-cigarettes users also still smoke (which is true), e-cigarettes must not really be helping people quit. FDA could be interpreted as relying on such a claim by innuendo in their draft rule, though without out-and-out making the claim. The conclusion obviously does not follow from the observation. E-cigarettes have still helped many quit smoking entirely, despite others only engaging in partial substitution.

Moreover, partial substitution for smoking still means less smoking, and thus less harm from smoking. Smoking less is not nearly as healthy as quitting entirely, but it is clearly healthier than smoking more. Some commentators try to distract from this with innuendo that these “dual users” (to use the usual rubric from the innuendo) are somehow worse off merely because they are using two nicotine products rather than one. But there is literally no reason to believe this is the case. FDA agrees: They removed the former warnings on NRT products that incorrectly told smokers that using NRT while they continued to smoke created additional risk.

Many e-cigarette users who still smoke are on their way to quitting entirely. Indeed, many smokers who try an e-cigarette without the intention of completely switching find that vaping is sufficiently attractive that they become “accidental quitters.” In our member survey, 11% of those who quit smoking by switching entirely to e-cigarettes had no intention of quitting smoking entirely when they started using e-cigarettes, but did so anyway. Moreover, for those whose goal is total abstinence from all nicotine products, but cannot bring themselves to quit unaided, e-cigarettes are a useful bridge. E-cigarettes are not going to prevent them from becoming abstinent and, indeed, many former users who could not stand the thought of quitting smoking find that after they switch to e-cigarettes, quitting both products entirely is much easier (quantification of this phenomenon is limited, but it clearly is not rare). In any case, any smoker who is using e-cigarettes some of the time is a much better candidate for smoking cessation than is a smoker who has never tried them. In other words, “dual use” is a benefit, not a cost.

Some e-cigarette detractors go further still and make completely unsupported claims that e-cigarettes actually interfere with smoking cessation. Usually this takes the form of claiming that they are sometimes used by smokers as a temporary substitute when they cannot smoke, and thus make it easier for them to remain smokers. Even setting aside the grossly unethical premise (that a proper role of smoke-free place laws is to cause smokers to suffer so much they are forced to quit), it is clear that proponents of this argument do not really believe this rationalization. If they did, they would also call for bans on NRT, which has been used much longer and by more

smokers for exactly this purpose. They never suggest such bans, or even restrictions on NRT's availability and marketing. In any case, some e-cigarettes and NRT will continue to exist so even if this were a problem, it would not be affected by the proposed rule, and thus is irrelevant.

Sometimes claims about e-cigarettes causing smoking are ostensibly based on evidence, but this invariably consists of cherry picking the two or three studies that studied people who tried e-cigarettes but did not subsequently quit smoking, observing they are less likely to quit (under particular later circumstances) than the average smoker. But this is obviously going to be the case because of the biased selection of individuals who are so dedicated to smoking that they tried e-cigarettes (and presumably various other methods) and still could not bring themselves to quit smoking. It in no way suggests the e-cigarettes are causing continued smoking.

Similar anti-scientific claims are based on the general observation that most people who quit smoking just do so without a substitute or other assistance. But that is because people are different.<sup>7</sup> Smokers who are willing and able to quit unaided just do so, and the availability of e-cigarettes does nothing to interfere with this option. But many need help, and e-cigarettes are purpose-built to provide that help, and are very effective at it. It is also important to keep in mind that those smokers who choose to only partially substitute e-cigarettes are doing so by choice; they always have the option of just smoking, quitting everything, or switching entirely to e-cigarettes -- which they are now familiar with, and thus might be enticed to switch entirely if they found the right product (or it was invented). Given that they are familiar with the different options, we can infer from revealed preferences that they are making the choice that maximizes their welfare, even if it harms their health (one of many contributors to welfare) compared to switching entirely.

In any case, even if "dual use" really did create problems, or even if somehow the availability of e-cigarettes were causing people who would have preferred to quit to keep smoking, the proposed rule would not solve this problem. The particular products that received approvals to stay on the market would be exactly the closed-system cigalikes that are best suited for occasional "dual use." Open systems appear to be the most effective for attracting smokers to switch entirely. Tobacco- and menthol-flavored cigalikes, on the other hand, are most appealing to current smokers, and due to being small and cheap for occasional use, are conveniently suited for the much-derided purpose of providing a temporary substitute for a smoker who is not trying to quit or even cut down, but cannot smoke where he is. This is not to say that cigalikes are not a viable complete substitute for some smokers and a transition product for many others; they are a valuable contributor to public health and consumer welfare. The point is that if there really were legitimate concern about e-cigarettes sustaining smoking, it would argue for banning cigalikes and allowing open systems to remain legal to sell, rather than the other way around. What is

<sup>7</sup> See: <http://ep-ology.com/2014/11/24/working-paper-phillips-nissen-rodu-understanding-the-evidence-about-the-comparative-success-of-smoking-cessation-methods-choice-second-order-preferences-tobacco-harm-reduction-and-other-neglect/> for more details about different types of quitters and the confusion that these differences can create.

worse, to the extent that the rule or subsequent FDA action did discourage “dual use,” the inevitable result would be many of those consumers just settling for smoking only.

Claims that e-cigarettes have a “gateway” effect or “renormalizing” smoking -- that they cause would-be never-smokers to become smokers -- are even less legitimate. Again, this is a case where FDA invokes the rhetoric about such effects by innuendo without actually making any concrete (and thus challengeable) claims. These claims focus on adolescents (no one seriously suggests that adult nonsmokers will take up smoking) and are presented with a tone that implies it is self-evident that these phenomena would occur. But a moment of thought makes clear that each is actually extremely unlikely on its face, and thus these are extraordinary claims that call for extraordinary evidence, evidence which does not exist.

How can people ostentatiously *not* smoking, and demonstrating that they are willing to seek out an alternative in order to quit smoking, possibly “renormalize” smoking? There is no apparent answer to that. Well over 15% of the population still smokes, even after many have switched to e-cigarettes, so it is not as if e-cigarettes are what makes smoking normal.” Moreover, since e-cigarettes are used as a substitute for smoking, they *replace* the action that genuinely does “normalize” smoking. Some proponents of this claim point to evidence that suggests that adolescents with more exposure to e-cigarettes are more likely to think smoking is normal, but this is simple selection bias -- this is the subpopulation that is also more exposed to smoking. There is simply no evidence that such “renormalization” is occurring and no reason to believe it will. Moreover, once again, if it were really a valid concern, the proposed rule would do nothing to stop it.

Similarly, it is apparent that the gateway claim is much closer to completely absurd than self-evident. Why, exactly, would someone who would have chosen abstinence over smoking in a world without e-cigarettes change their mind as a result of discovering they like e-cigarettes better than abstinence? The claim is that his original preference to prefer smoking over abstinence is somehow reversed by the availability of a third option. He could have chosen to smoke in the first place, after all, but presumably realized there were good reasons to avoid it that did not extend to the e-cigarettes he did choose to use; those motivations are not going to change. Moreover, the claim requires that he also decide he prefers smoking to the e-cigarettes that he discovered he likes, and by enough that it is worth accepting the much higher risk that he originally wanted to avoid. This is an extremely unlikely pattern of preference change, about as far from self-evident as can be imagined.<sup>8</sup>

Not only is there no extraordinary evidence in support of this extraordinary gateway claim, there really is no evidence at all. What is often claimed to be evidence for this phenomenon is simply

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<sup>8</sup> The observations presented here about the gateway claim are examined at length in <http://www.mdpi.com/1660-4601/12/5/5439>.

the observation that teenagers who try or use e-cigarettes are more likely to be smokers or engage in other genuinely harmful behaviors. But this provides no support for the gateway claim, that e-cigarettes are causing smoking. Indeed, this association is exactly what we would expect to see if teenagers were mainly using e-cigarettes for harm reduction, which seems to be the case. The association would also be observed merely because individuals who choose to engage in one prohibited or discouraged behavior are also more likely to engage in another, which is clearly the case. Indeed, if the data is analyzed seriously (as is done in the paper referenced in the footnote), it fails to show the specific patterns we would expect if there were a gateway effect. What we can really conclude from this association is that e-cigarettes are undoubtedly crowding out other more harmful behaviors.

In any case, if there really were problems of “renormalizing” or gateway effects, the proposed rule would have no apparent potential to reduce them, given that it would not actually reduce adolescents’ access to e-cigarettes, as assessed below.

#### There is no history of serious manufacturing problems

Even though e-cigarettes are low risk, if there were a history of manufacturing errors that harmed consumers, this would be a legitimate justification for real regulation. FDA regulates food manufacturers to reduce the common problems in that sector. However, unlike with food manufacture, there have been no documented cases of major manufacturing problems that caused an “outbreak” situation. While it is certainly possible that such a problem could occur, and there would be value in reducing the risk, the lack of real occurrences suggests the potential for improvement is minor. There are incidents of injurious failures of batteries and charging systems, which could theoretically be reduced by better regulation, but the total magnitude is small. It is certainly not sufficient to warrant a ban.

The claims about potential manufacturing problems are always just that, about the *potential*. Moreover, the proposed ban would not actually reduce these risks since the alternative markets would undoubtedly create much greater risks, as discussed below.

#### Implication of these basic facts

The low risk from e-cigarettes and the limited history of manufacturing failure mean that the prospects for regulation to make e-cigarettes less risky for consumers are minimal. The low risk and the fact that e-cigarettes serve as a substitute for smoking mean that there is no legitimate reason to aggressively discourage e-cigarette use. The claims about the existence of e-cigarettes causing smoking are far-fetched, but in any case no regulation could plausibly change this. In sum, the maximum theoretical benefits for adult consumers of e-cigarette regulations are extremely modest. (The issue of underage use is addressed separately below.) Moreover, FDA has not offered even an assertion about how this rule will actually make *any* improvements. This makes the intervention that is proposed -- the *de facto* ban of the hundred-thousand-plus products currently on the market -- an extreme “solution” in search of a problem. Even without

considering the unintended consequences -- the reduction in smoking cessation, the black market, and the other observations that follow -- there is no compelling public need that warrants such a draconian interference in the free market.

#### **FDA regulation of tobacco products: processes, policies, and history**

FDA does not really regulate cigarettes and smokeless tobacco now, and would not regulate e-cigarettes under the deeming -- not in any normal sense of the word "regulate." As already noted, FDA authority over tobacco products is a creeping prohibition, not real regulation. The FDA rules and actions are simply designed to gum up the market, with technology freezes, paperwork burdens, and fees. Whatever one might think of the ethics of this approach to public policy when it comes to cigarettes and the harms they cause, it is clearly not appropriate for products that pose minor risks. This is especially true given that the free availability of low-risk alternatives actually *further*s the ostensible goal of FDA regulation, to reduce smoking and improve public health. FDA authority has done basically nothing to discourage the use of cigarettes. For cigarettes, the 2007 grandfather date simply protects the incumbents from competition (and so the TCA is often called the "Marlboro Protection Act"). But applying the same rules to e-cigarettes would destroy that market.

FDA has imposed no regulations of consequence on cigarettes beyond freezing introduction of new products. The TCA itself included a federal law against underage sales (which is redundant with state laws), some labeling rules, and a ban on characteristic flavoring for cigarettes (which were a trivial part of the market). Beyond that, FDA has done no real regulating. There is constant discussion about someday imposing some real regulations, like limiting quantities of particular chemicals that some believe to be independent sources of health risks, but there is nothing like that now and there may never be. This is regulation only if that is defined so broadly as to include any limit on commerce, and thus would include alcohol prohibition.

#### FDA has a demonstrated history of interfering with harm reduction in their regulation of smokeless tobacco

While it is arguably difficult to regulate cigarettes usefully, FDA still has had the opportunity to reduce smoking by encouraging harm reduction. FDA says it recognizes tobacco harm reduction and the value of encouraging people to shift from cigarettes to low-risk alternatives, but their actual behavior would suggest a lack of interest on acting upon this.

The TCA granted FDA authority over smokeless tobacco (ST) products. So predictions about how FDA will really treat a low-risk product like e-cigarettes need not be evidence-free speculation. It is useful to review past behavior to gain an understanding of what concrete actions FDA is likely to take regarding e-cigarettes. Some observers have suggested that FDA's pro-harm-reduction rhetoric means they will endeavor to undo the resulting damage from the blanket

ban that the deeming would impose. FDA's history suggests that this is an indefensible prediction.

The popular versions of ST in the USA are estimated to be 99% less harmful than smoking. This is based on ample real epidemiologic evidence. It is extrapolation from this evidence that allowed FDA pharmaceutical regulators to conclude that long-term use of NRT is close to harmless, resulting in allowing long-term use to be "on-label." It is also this that allows us to conclude that the risk from e-cigarettes is probably also similarly low. Some experts believe ST use is actually net beneficial to health, with the known protections against neurodegenerative diseases outweighing any cardiovascular risk. Without going into the uncertain details there, it is sufficient to observe that ST is a very low-risk alternative to smoking. It is reasonable to predict it is a bit lower risk than e-cigarettes, given the (minor) uncertainties surrounding the latter.

FDA has used their authority over this proven low-risk alternative to discourage harm reduction. They have helped maintain the myth that ST is high risk (thus dissuading smokers from switching) and have been as unwilling to allow improvements in those products just as they have with cigarettes.

The U.S. government has long been the leading source of the myth that ST users might as well smoke by sowing disinformation that implies the risk from ST use is as great as that from smoking.<sup>9</sup> While this predates FDA regulation of tobacco products, the FDA tobacco regulators work hand-in-glove with the CDC, which has long been the leading source of this myth and is also leading efforts to vilify e-cigarettes. FDA has done nothing to combat this misinformation despite their claims that their regulation encourages switching to lower-risk products.

The TCA was designed, intentionally or otherwise, to discourage harm reduction behavior. Some commentators are fond of saying that the TCA was designed to create enormous burdens for the high-risk product (cigarette) market, and therefore it is not appropriate to include e-cigarettes. This is half right. The TCA creates burdens for the cigarette market and it is a terrible idea to subject e-cigarettes to the same provisions. But the TCA imposed the same burdens on low-risk alternatives to cigarettes. ST was explicitly included and intentionally subject to the same burdens as cigarettes. The TCA imposed four rotating "warning" labels on ST products which grossly overstate their risks. One of them is specifically designed to discourage THR: "This product is not a safe alternative to cigarettes." Though a careful literal reading says otherwise, this is clearly intended to communicate, and is generally read as saying, that ST is no *safer* than cigarettes.

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<sup>9</sup> This was documented before the dawn of e-cigarettes in <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1090592/>.

One might argue that FDA really believes their repeated claims about supporting harm reduction, but their hands were tied by the TCA. If that were true, it would offer little reassurance about balanced regulation of e-cigarettes. But FDA has had opportunities to favor ST products over cigarettes, but has repeatedly avoided doing so.

Swedish Match (SM), the leading ST company in Sweden but a small player in the USA, spent millions of dollars filing a “modified-risk tobacco product” (MRTP) application seeking to remove two of the labels that are clearly unsupported by the science (about causing oral cancer and dental diseases), and to change the one quoted above to, “No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.”<sup>10</sup> The decision on that is still pending, but the FDA hearing on the subject suggested intense hostility toward allowing this change, despite there being no argument made that the existing labels are accurate or beneficial.<sup>11</sup>

But what is really telling about FDA’s view of promoting harm reduction is that they could have chosen to accept a much better version of this applications (or pick and choose parts of it if they preferred), but refused to do so. Even if the entire application is accepted, it will apply only to SM’s products, and there is little chance anyone else could make a similarly strong MRTP application (for reasons explained in the above references), even though there is no evidence that SM’s products are lower risk than the ST variations that are more popular in the USA. But FDA had the opportunity to remove the disinformation from the warning labels for the entire category when Reynolds submitted an earlier application for the same changes via a more *ad hoc* process. FDA denied the request and told them they must do a full massive MRTP application instead (SM’s application was 130,000 pages long), which would then apply only to the specific Reynolds products covered in the application.<sup>12</sup> But if FDA had wanted to promote THR, they could have decided differently -- again, all of their decisions about applications are free-standing policy decisions because they have defined no rules that constrain their choices.<sup>13</sup>

One might argue that these applications are just too visible and too associated with “big tobacco,” and that FDA simply did not want to deal with the harsh criticism from tobacco control extremists if they had decided differently. This explanation should offer no reassurance about FDA acting in the interests of real public health in the future, however, since that is the exact

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<sup>10</sup> Further details can be found at: <http://antithrlies.com/2014/06/14/why-the-most-important-ecig-news-of-the-week-is-swedish-matchs-mrtp-application/>. CASAA filed a comment in support of the application: <http://blog.casaa.org/2014/11/casaa-comment-to-fda-regarding-swedish.html>.

<sup>11</sup> See: <http://antithrlies.com/2015/04/12/tpsac-meeting-on-swedish-match-mrtp-application-is-there-a-scientist-in-the-house/>.

<sup>12</sup> <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm446663.htm>

<sup>13</sup> It is worth noting one particular absurdity inherent in this process: Consumers can only be given accurate information about harm reduction if a tobacco company judges it to be in their best commercial interest to spend the money to apply to be able to tell the truth.

same criticism they will face if they take the affirmative steps necessary to avoid effectively banning e-cigarettes. Furthermore, that explanation does not stand up to other observations about FDA behavior.

Last year, FDA ruled against a “substantial equivalence” (SE) application for the Ariva/Stonewall line of dissolvable ST products made by a very small manufacturer that has never been in the cigarette business. Most experts guess that these lozenges are the lowest risk tobacco products on the market (they have less of some chemicals found in ST that might cause some immeasurably small cancer risk), and their unattractive form and appearance, and their lack of marketing, mean that they only appeal to a niche of would-be smokers who learn about them. These are perhaps the least glamourous tobacco product in existence. The application, which merely asked permission to keep selling some new flavors, was denied by FDA. Moreover, FDA then aggressively went after retailers who still had the new flavors on their shelves rather than just quietly letting them sell off their stock.<sup>14</sup>

FDA rationalized their decision on the grounds that one relatively unimportant molecule was present at greater concentration and thus the new flavors were not equivalent enough to be “substantially equivalent,” and seemingly also because the application did not offer evidence that the new variations would not attract any non-users of tobacco to use them. But *any* change in a product will increase the concentration of at least one molecule, and it is literally impossible to offer evidence that a product introduction or change will not attract any new users. But, again, these decisions are arbitrary and so FDA could have issued the opposite decision. This was purely a policy decision against a product whose only apparent niche is for harm reduction.

It is a challenge to be forced to analyze a proposed regulation not in terms of its actual technical requirements, but by assessing attitudes and preferences of actors. But that is exactly what must be done in the present case because the arbitrariness of FDA tobacco regulation means that all the details come down to their preferences. FDA could theoretically choose to try to ameliorate the destructive payload built into the deeming itself, or it could choose to make it as harmful as possible to the e-cigarette market and the public health benefits it creates. Some observers suggest that they must be planning the former moderation because of their rhetoric, but this assumption is not at all supported by FDA’s actions to date.

#### FDA processes under the TCA are really supplication, not regulation

This general point has already been made, but some further details are in order. Prospects are far worse for e-cigarettes than they are ST. The FDA is prevented from just banning an existing ST

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<sup>14</sup> For more information on these events, see: <http://antithrlies.com/2014/08/31/fda-signals-that-nothing-is-ever-substantially-equivalent/> and <http://antithrlies.com/2014/11/20/fda-proudly-harasses-retailers-for-selling-lowest-risk-products/>.

product from the market except via actual product regulations (and there is no evidence that they are seriously pursuing any such). The new varieties of the aforementioned ST lozenge were banned, but the grandfathered versions of the product were allowed to stay on the market. But FDA will ban all e-cigarette products from the market because none of them will be grandfathered. In addition, there are rumors that they will try to accelerate that ban for many e-cigarette products, imposing it even before the grace period for the blanket ban.

As already noted, there are no real regulatory standards in sight, nor any that are likely to be developed, such that a manufacturer can meet them and be confident its product will be allowed to stay on the market. FDA also has never provided clear instructions for any application, though they make it clear that an enormous pharmaceutical-style application is in order, with *de novo* research on the particular individual product rather than generalization from other similar products. FDA is then free to take these massive and expensive filings and make any decision they want.

The lack of procedural rules and lack of clear product standards mean that the PMTA process is basically just supplication. It is the price of admission to be eligible for FDA to hand-pick the product for approval, or not. The FDA application guidance documents are sufficiently vague as to allow almost anything. Representatives of industry have stated (personal communication; this is impossible to document for obvious reasons, though public pronouncements of these claims at conferences seem to surprise no one) that about three-quarters of the applications to FDA by currently-regulated tobacco companies are rejected (i.e., they refuse to make a decision on the application as submitted) or denied by FDA based for reasons the applicant had no way of anticipating. That is, the bases for the rejections and denials were never identified as required information or product standard in any FDA public document or in direct communication with the manufacturer. It is not an exaggeration to characterize the instructions for PMTA applications as saying “do all this -- or not, your choice -- and we will then accept the application or bounce it back for more information -- our choice -- and if we accept it we will make a final decision based on something.”

Granted, any regulatory process that involves complicated science is going to have some fuzzy edges. The FDA drug approval process, which the FDA tobacco regulators are inappropriately trying to mimic, inherently includes the necessarily subjective step of deciding whether the imperfect body of available evidence is convincing. But at least there are pretty good rules and a consistent pattern of constructive engagement with the regulated companies to try to deal with the fuzziness in ways that (mostly) serve the public interest. The major tobacco companies can afford to maintain constructive engagement with FDA, but no more than a handful of other companies in the e-cigarette sector have that capacity (and there is no representation whatsoever of consumers’ interest). Even with that engagement, though, given the expense and vagueness of

the PMTA process, it is easy to believe that even the big companies with individual products whose sales could justify the PMTA application expense (which would only be mass-market closed-system cigalikes) might not want to bother with it. In sum, the PMTA option as it currently exists should not be seen as making this rule anything other than a blanket ban.

The only exception is likely to be purely political: FDA probably wants to grant a few e-cigarettes approvals in order to be able to claim that they are not really banning the category. Thus it is likely they will hand-pick a few winners. In the event they do not even get enough applications to meet their goal, they can persuade the companies they regulate in other tobacco product sectors to file them.

FDA has offered no reason to believe their approval processes will be any different for e-cigarettes

FDA has tried to imply that e-cigarettes will somehow not be subject to such a prohibitively expensive and arbitrary supplication process. But they have offered no indication of how they will actually bring this about. In the absence of a binding commitment by FDA to adopt clear, attainable, and not cost-prohibitive rules for e-cigarette PMTAs -- which would require actually writing them and including them, at least by reference, in the proposed rule -- the rule must be evaluated based on FDA's demonstrated behavior. Vague promises about intentions to do something that fix the damage that is being done are insufficient given the huge social, financial and health costs associated with the deeming.

It is difficult to imagine FDA would, or even could, write such rules for submitting applications and standards for ruling on them. FDA tobacco regulators have never before written any such rules, and have shown no inclination to *ever* make a concrete statement -- about anything -- that says "this is good enough" or "if you do X then we will do Y." Without such concrete rules, the process will remain arbitrary.

Moreover, it is difficult to imagine any incremental change from FDA's current practice that would not still destroy the diverse legal market for e-cigarettes. The processes are far beyond the resources of small businesses. It would require a huge departure from FDA's pharmaceutical-style approach to regulating tobacco products for them to accept applications for parts of open-system e-cigarettes, particularly including the liquid, since it is impossible to test these products under the many product configurations in which they might be used. The cost of most imaginable testing requirements, beyond the basic purity and functionality testing that is part of a good product process, would be sufficient to *de facto* ban most of the open-system products on the market.

### **The real result of the attempted *de facto* ban: Emergence of alternative markets**

Contrary to the fiction implicit in the proposed regulations that e-cigarette products currently not approved by FDA will simply cease to exist, it is obvious to any honest and informed observer that this will not be the case. Instead, there will be a vibrant black and shadow market. In the draft version of the rule, FDA stated that “greater regulatory certainty created by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved products will enter the market without having to compete against equally novel, but more dangerous products.” This statement is simply not true on two levels. The products will still have to compete with those in parallel markets, and the parallel markets are likely to be far more innovative and cheaper because they are not subject to FDA’s glacially slow and prohibitively expensive approval process.

Many of the myths surrounding tobacco product consumption are predicated on the fiction that supply creates demand rather than the other way around. Anyone who understands that there is demand for e-cigarette products (as there is for tobacco products in general) realizes that this demand will not magically disappear when FDA asserts jurisdiction over the supply. The reality is that the products that exist now will continue to exist, and will be available in a market that is far less regulated and safe than the *status quo*. E-cigarette products, in the variety and quality that currently exist, provide enormous improvements in consumer welfare (including the health benefits of providing an attractive alternative to smoking), and this creates demand that will not be eliminated by fiat.

Our recent survey results show that when presented with any of three scenarios that describe potential FDA rules (a total ban on e-cigarettes, a market that consisted just of a few tobacco/menthol flavored cigalikes, or a ban just on flavors other than tobacco/menthol), 90% of the respondents indicated that they would expect to continue to use whatever products they are using now. Respondents indicated the intention to acquire the necessary products through black or shadow markets, self-importing, or making them themselves. The survey population is almost all open-system users, and are probably fairly representative of most experienced users of those products. But there would probably also be an alternative market for closed-system products that were cheaper and came in a better variety of flavors than the products available from the legal oligopolists.

If it appeared that FDA regulation would actually eliminate the supply of e-cigarette products, we might expect “ACT-UP”-style direct action. An effective ban would be so important to hundreds of thousands of Americans that they would take to the streets. But there is no serious talk of this because most everyone who would take such action is confident they can simply circumvent the ban. They still hate it at a “single issue voter” level (imposing this regulation could swing most of a million votes against the Democrats in the 2016 election, due to the common public perception that Democrats are responsible for the proposal, and far more if the

Republican presidential nominee expressed some support for e-cigarettes). But these dedicated vapers realistically expect there is an easy way to reduce the barm that is heing imposed on them by using alternative markets.

#### The nature of the continuing market

It is not difficult to predict the response to the proposed ban by manufacturers and consumers. There appear to be a few million vapers already using open-system e-cigarette in the USA, and there will be many more before the ban takes effect after a grace period. This huge demand will continue to attract supply.

The continuing market for e-cigarettes in the USA, under the proposed regulations, will contrast with the minimal markets for banned or almost-banned low-risk tobacco products, such as snus in the European Union (EU). In the case of snus in the EU, snus is generally available to consumers who seek it, but obtaining it is not convenient, and the ban appears to have reduced awareness about the advantages of snus and so has kept it from becoming a popular alternative for smokers in subpopulations who did not use it traditionally. By contrast, e-cigarettes are already very popular as a smoking cessation method and alternative in the USA, there is an established strong social network associated with them, and there is near universal awareness of them. Moreover, the proposed ban would only regulate sales, and not be a full-on ban that criminalizes acquisition, usage, or manufacture (absent sales). Thus there will be very little legal exposure in continuing to use the products openly, and social networking around them will not be hindered. These factors also mean that the regulation will create very little, if any, social stigma; in some cases, making something illegal causes people to think of it as immoral, but there is little chance of that occurring here. These factors do not change the fact that alternative markets will be inferior to the *status quo* in many ways, and will probably only modestly mitigate how much the rule discourages current smokers from quitting via e-cigarettes and encourages less-committed e-cigarette users to switch back to smoking. But they do ensure that current e-cigarette enthusiasts will not hesitate to embrace alternative markets.

The exact nature of the new market will depend on exactly which products FDA asserts jurisdiction over. It does not appear that FDA will be able to sustain any attempt to ban e-cigarette liquids that do not contain nicotine (or other chemicals derived from tobacco plants) under the TCA, though they might still attempt to do so and invite the inevitable lawsuits. Under the scenario where FDA does not even attempt this, or where manufacturers win a stay and ultimately vindication through the courts, current manufacturers of the liquid will be able to continue to make and market zero-nicotine versions of their current products. Given that many manufacturers have acquired industry-specific skills and infrastructure and have developed brand equity in the sector, it is inevitable that many will stay in the market on this basis, though most will be forced to dramatically downsize because they can no longer openly sell nicotine-

containing liquid, the majority of their business. (Additional legislation could be passed to enable FDA to regulate these tobacco-free products, perhaps as foods. This could theoretically even be good for consumers, if food-style purity and safety (i.e., real) regulations were imposed. But given the popular uprising against e-cigarette regulation and the political trends in Congress, such action seems rather unlikely.)

Another crux question is whether FDA attempts to assert authority over e-cigarette hardware that is sold independently of the liquid, and whether this would ever be upheld by the courts. If FDA lacks jurisdiction over zero-nicotine liquids, it seems impossible that they could assert such authority. Hardware manufacturers will have an easy option of continuing to market their products, duly labeling them as “not for use with nicotine-containing liquids.” It seems unlikely that such sales could be prevented on the basis that some of the hardware is being diverted by consumers to use with nicotine-containing liquid. Consider the historical inability to ban products that were clearly designed to smoke cannabis because they were sold under the transparent fiction of being tobacco-smoking devices. Moreover, ironically, since most e-cigarette hardware components can be used for the consumption of increasingly-legal cannabis, the increasingly legal cannabis market will create an additional safe-haven for hardware sales, and also ensure that the powerful cannabis lobby will join vapers in opposing new laws that restrict hardware sales.

Thus, there are three basic scenarios. The most likely of these appears to be that FDA is ultimately unable to regulate either open-system hardware or zero-nicotine liquids. That leaves open-system consumers in need of only the nicotine-containing liquid, which can easily be supplied in any of several ways.

The first option is a black market for the same e-cigarette liquid varieties that are available now, which is inevitable given the large number of tiny domestic manufacturers that exist and have local distribution networks, and the social networking surrounding vaping. It would be easy for such small manufacturers to stockpile years' worth of nicotine, and probably not much harder to continue to untraceably acquire it. Foreign manufacturers -- existing or new -- who are not seeking FDA approvals and are in jurisdictions where the U.S. FDA has little influence would have no incentive to not ship to U.S. consumers. The products are sufficiently inexpensive that the risk of Customs seizure would be tolerable. The supply chain for “street corner” black-market e-cigarette liquid sales would be easier to operate than that for popular banned drugs, products which are easily available to consumers who seek them, and the distribution network could be spared. The risks involved would be less than for suppliers of those other products, given that possession would be legal and it is unlikely that draconian anti-drug punishments would be replicated for selling e-cigarette liquid. However, there would still be some risk, and thus prices would rise to provide a risk premium for suppliers.

The second possibility involves legal sales of non-banned liquid. If the rumor is true that FDA will seek to ban appealing flavors before the total ban takes effect, there will be a window in which this is relevant even if, as seems likely, FDA would never approve any open-system liquid under PMTA. In a situation where some liquids remained legal for sale, manufacturers would undoubtedly offer an unflavored variety and sell flavoring products designed to be mixed with it (which would be clearly outside FDA jurisdiction under the TCA). Alternatively, consumers could mix legal unflavored nicotine solutions with legal flavored zero-nicotine liquid.

A hybrid version of these two market possibilities is a black/import market in unflavored nicotine solution, with nicotine concentrations that are optimized for easy mixing with legal zero-nicotine liquids. These products are already sold for do-it-yourself (DIY) mixing.

The third method, which would also be impossible to stop, is DIY nicotinization of the liquid or full-on DIY manufacture. A year's supply of nicotine for a typical e-cigarette user is in the order of 10 g, about two teaspoons. This would be trivial to distribute and stockpile, or smuggle if necessary. Smuggling might not be necessary, given that nicotine is not now a controlled substance and it is not clear whether it would be covered under the deeming given that pure nicotine is a manufacturing input for e-cigarettes but is not a consumer good in that form. While major nicotine manufacturers are unlikely to enter this business, it would not be difficult for some of their corporate customers to stock up and divert the nicotine to the consumer market. If nicotine remains legal, the logistics are simpler, but a ban would be a fairly minor obstacle.

While the process for mixing the highest-quality (and safest) e-cigarette liquid requires artistry and engineering skill, mixing e-cigarette liquid can be done at home by most anyone with easily available ingredients. It already occurs to a sufficient extent to provide proof-of-concept.

Under the scenario in which FDA succeeds in banning sales of zero-nicotine e-cigarette liquid, some of these paths would be precluded, but others would remain. Under the scenario where hardware sales were also banned, the black market, import, and DIY options would simply have to be expanded. Most dedicated open-system users have enough hardware to last for many years with only some minor and simple maintenance needed. The parts for upkeeps are easily available as electronic supplies that FDA could not possibly interfere with. The same channels would supply parts that could be used to build entire devices from scratch. As with the liquid, these devices would be lower quality than those available in the current market, possibly including creating greater health risks, but they would be quite adequate.

While interest in actively seeking out alternative markets is probably associated strongly with using open systems, an alternative market in closed-system products is also inevitable. A wider

variety of cigalikes than will be available in the legal U.S. market will continue to be produced elsewhere, particularly including a wider variety of flavors. Self-import will be possible for those cigalike consumers who prefer their current products, and only a dramatic increase in Customs enforcement could slow this. Some among the existing network of neighborhood black marketeers (i.e., cigarette bootleggers and drug dealers) would probably discover that there was demand for these products, particularly since they could probably undercut the price of the legal oligopoly, and thus they would add them to their product line.

#### Consequences of the new market for e-cigarette products

The result of banning the legal e-cigarette market will be *less regulation* and *greater risk* than currently exists, and it would also foreclose the opportunity for good real regulation to create benefits. By forcing consumers into alternative markets, the rule will result in substantial negative consequences for consumers compared to the *status quo*, though the net harm will be substantially less than it would be without the alternative markets.

First, DIY manufacture or mixing will increase the risk of accidents. Hundreds of thousands of vapers possessing and handling pure nicotine would dramatically increase the accidental poisoning hazard posed by e-cigarettes. Despite the engineered hype about accidental poisonings that exists now, the current risk is very close to zero due to the low toxicity of e-cigarette liquid.<sup>15</sup> That would not be the case for pure nicotine. Despite the hype, apparently the only case of a fatal accidental poisoning associated with e-cigarettes was from a toddler getting access to a very high-concentration nicotine solution used for manufacturing. Current DIY mixing enthusiasts typically uses lower-concentration nicotine solutions because it is easier and safer, but if the nicotine must be acquired through the black market, there will be incentives to minimize cost and confiscation risk by buying smaller volumes of high-concentration solutions or even pure nicotine, and diluting them with legal ingredients. There is even interest in DIY extraction of nicotine from tobacco leaf. Although most consumers who are toying with this idea will abandon it when they discover how difficult it is and how easy it is to get nicotine on the black market, any attempts will further increase the hazards created by the rule.

As is typical for prohibitions of drugs that people choose to use, the DIY market also presents far greater risks of accidental overdose than a legal market would. There is no formal quality control and the risk of badly erring in proportions is much greater due to the smaller quantities and lack of experience. Once again, one of the frequently hyped engineered concerns about e-cigarettes – that nicotine concentrations sometimes vary somewhat from what the consumer intends to use – would be dramatically exacerbated by the supposed solution. FDA claimed in their draft version of the regulation, “users who expect consistency in these products may instead be subject to

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<sup>15</sup> For more on this, see CASAA’s comment on FDA’s proposed mandating of child-resistant packaging, at <http://blog.casaa.org/2015/09/casaa-comment-on-fdas-proposed.html>.

significant variability in nicotine content among products," though the reality is that there is no serious problem and the evolving branded marketplace (and marketplace of information) is effectively correcting such problems to the extent they exist. DIY (and to a lesser extent, the black market) would *create* the problem that FDA claims to be solving. Moreover, with so many people mixing their own liquids, it is inevitable that some will try adding ingredients that no reputable manufacturer would use, and that would increase health risks.

Second, the existing *de facto* regulatory system, which has proven quite effective so far, would be hugely eroded. The current rhetoric about "there is no regulation" or that the e-cigarette market is "the Wild West" ignores not only the many command-and-control regulations that already do apply to these products, but also the fact that regulation of all consumer goods in the USA relies substantially on brand equity and the civil liability system. The benefits of these effective regulations would be dramatically reduced when the ban eliminates the legal markets.

For obvious reasons, full-on black marketeers gain limited net benefit from building brand equity. They have incentives to avoid consistent branding, and the value of developing a good reputation is capped by their need to stay small enough to escape serious scrutiny. They are generally impossible to sue should something go wrong. To a lesser extent, the same factors will reduce the brand equity incentives for manufacturers of hardware or liquid products for the legal shadow market.

Even as the FDA approval process favors only the largest companies, the evolving black and shadow markets will almost certainly favor *ad hoc* small domestic producers -- someone can produce enough e-cigarette liquid or hardware to make a living on their kitchen table -- over the existing medium-sized domestic manufacturers that tend to have better quality control. If existing medium-sized e-cigarette liquid companies stay in operation to make zero-nicotine liquids, they will still lose the large part of their business that is nicotine-containing liquids, which will force downsizing and cost-cutting. The regulations will create a climate of risk for manufacturers -- obviously for the black marketeers, but also for the shadow markets where there will be constant fear of new regulation or government enforcement actions, which are financially devastating even when they are unlawful and cannot stand up to court challenge (as evidenced by the financial devastation inflicted by FDA unlawfully directing Customs to seize e-cigarette products in 2009). This will discourage investment in the physical facilities and brand equity that lead to higher quality and safer products. There will also be a reasonable fear that greater size will attract more scrutiny.

These disincentives for investment and growth -- making investment risky, favoring tiny producers over larger ones, and destroying brand equity -- will also slow the remarkable month-to-month quality improvements in the technology. While black- and shadow-market producers

will inevitably continue to innovate far more than the FDA-regulated sector will be allowed to, and will take advantage of innovations from elsewhere in the world, improvements in safety and quality control will no longer be as well rewarded. The rewards for innovation might shift further away from such qualities and toward “gadget factor” whimsical innovations that appeal to the existing core of users rather than current smokers. There are, of course, rewards for the latter type of innovation now -- and those who express concerns about e-cigarettes seem to find this to be bad -- but they will become relatively stronger. Driving most of the market into a borderline-legal status will turn what is a rapidly maturing industry into permanent adolescence.

In short, most of the *de facto* regulatory protection and continuous quality improvement that is now in place will be lost, with no apparent offsetting benefit. Manufacturers that are currently motivated and able to produce higher-quality products will be disadvantaged compared to fly-by-night producers who can simply disappear if something goes wrong. The market for manufacture and distribution will favor those with high risk-tolerance and willingness to walk away, as with the illicit drug market, rather than those who are committed to long-term improvements in the quality (including safety) of the products, and possess more desirable skills and traits.

Black marketeers do not pay taxes. They also are generally more inclined to ignore behavioral standards or laws that prohibit sales to minors (the implications of this are addressed more below).

Finally, the establishment of a thriving black and shadow market will likely make future regulation more difficult and less effective. A time may come when a beneficial regulatory regime – one that is designed to genuinely benefit consumers by improving quality rather than hurt them by removing options, as the present proposal does -- is enabled and enacted. But by then, regulated legal manufacturers will have to compete against an established black and shadow market which consumers have become accustomed to using, and which will probably be able to maintain lower prices by avoiding taxes and regulatory paperwork.

For example, if it is ever discovered that particular ingredient or technology choice causes substantial health risk, a real regulatory system could forbid those ingredients in all e-cigarette liquid (with or without nicotine). But if such regulation is attempted after the currently proposed regulation creates a black and shadow market, it is likely that many manufacturers would undetectably ignore it. If such a discovery were made today, the suppliers who represent the vast majority of sales volume would voluntarily stop using the ingredient because they are respectable companies who care about their customers and their reputations. This effective self- and community-regulation would be severely weakened by the proposed regulations, which would largely replace the reputable companies with a black and shadow market.

To summarize, in just a few years, the market has evolved away from the "Wild West" characterization that represents much of the motivation for the proposed regulation, and it continues to evolve in a direction that is good for consumers and public health. Ironically, the only apparent way to stop such beneficial evolution, and thus to bring about the out-of-control market that exists in the politicized mythology, is to impose a rule like the current proposal.

FDA should have conducted serious research about the nature of the e-cigarette market that would emerge as a result of their proposed intervention. Their assessment of costs and benefits should have been based on that, not some unsubstantiated idea that any product they ban would just disappear from the market. Failing that, FDA needed only to have thought it through and talked to consumer representatives to understand what would happen. Indeed, we *explained* to them what would happen in our comments on the draft version of this rule. To the extent FDA has ignored alternative markets and their impact, including ignoring the analysis that was presented to them as comments, *all FDA claims about the implications of this rule are inaccurate.*

#### **There is no reason to believe this rule will further any of its ostensible aims**

With the preceding context established, it is possible to step through all of the stated and implicit aims of this rule and observe that *literally none of them* appears to be furthered by it. An intervention in the market, particularly one this draconian, can only be justified based on compelling public need and real concrete benefits. Yet as far as we can tell, this rule will create no benefits whatsoever. FDA has not offered even *prima facie* policy analysis that suggests that any goal will be furthered, let alone tried to quantify any supposed benefits.

#### Child-resistant packaging and warning labels

Consider the single substantive real regulation FDA has proposed that has the potential to benefit consumers: FDA circulated a proposed draft rule mandating packaging and warnings designed to reduce the risk of accidental poisonings of children. As we detailed in our above-referenced comment on that proposal, if done right it would be beneficial taken in isolation. We pointed out that the potential benefits are quite modest, given that the industry is shifting toward voluntarily using child-resistant packaging, and (as noted above) given that the number of harmful accidental exposures is small and appears to be declining even as the number of vapers increases. Thus this clearly does not warrant imposing a massively burdensome regulatory regime, let alone a ban. But a stand-alone version of this regulation would be appropriately modest and an easy rule to implement. Indeed, it has been proposed as stand-alone legislation.

But this is a perfect example of the type of good real regulation that would be foreclosed by shifting most of the market underground. If FDA manages to implement this particular bit of real regulation very rapidly, there will be a brief period where legal products are subject to it. After

the end of the grace period, when that market goes underground, the rule will lose all force. We would still hope that black marketeers and DIYers will take the sensible step of using child-resistant bottles for e-cigarette liquid, though this seems relatively unlikely (warning labels are obviously out of the question). There would be no way to enforce the requirement and the liability and brand-equity motives would be lost. Thus, the proposed ban would *eliminate* all of the potential benefits of having child safety regulation.

#### Inspections, oversight, and imposing good manufacturing practices

As we noted in our comments on the draft deeming regulation, FDA is palpably frustrated that they lack the authority to swoop in on a manufacturer -- to shut them down and gather information -- if there is an "outbreak" situation (e.g., poisonings from a batch of liquid) or other serious concerns about a major manufacturing problem. This seems to be one of their major motivations. In the draft regulation, FDA stated as part of the justification for the regulation, "Deeming would provide FDA with information on the location and number of regulated entities and allow the Agency to establish effective compliance programs."

Crisis response is a reasonable concern in principle, though it has never been a problem in practice. There has never been a detected case of an important contamination event for e-cigarettes like occurs in food production on an almost daily basis. So this is an ostensible solution to a problem that can be imagined but does not actually happen. If there had been a spate of such incidents, or even a few, some action to solve the problem might be justified. But the proposed rule would actually *decrease* the ability of the authorities to perform such an intervention and would further exacerbate the harms caused by such an unfortunate event.

Existing authorities can already deal with an "outbreak" event. If there were evidence that a manufacturer made a dangerous batch of liquid, state or local authorities would be quick to intervene, as would the CDC's EIS. Perhaps their exact legal authority for doing so might be a little fuzzy, but no one would try to stop them. There is no apparent way in which FDA registration could aid in this process; internet searches and social networking would reveal how to find or contact a manufacturer far more efficiently than the registration information. Moreover, any moderately reputable manufacturer would, upon learning of a problem, voluntarily cease production, communicate the news down their supply chain, and recall the faulty products. The existing social media networks would get word out to consumers and retailers faster and more effectively than any government agency could.

Of course, it is better to make sure procedures are followed to avoid such incidents rather than to respond to them (and, as noted, the lack of such incidents shows that this is being done). FDA's draft regulation implied that they could ensure such procedures, thereby protecting consumers and also ensuring that high-quality producers are not at a competitive disadvantage due to a

“lemons” problem. But they have given no indication of how they think they could do that. FDA has proposed no procedural standards and has provided no evidence they have identified what standards would make sense. They could just codify as law some of the industry-generated practice standards that have been developed. (There are controversies about those standards, but they do exist and could be adopted.) If that is the plan, FDA should make it clear and analyze the implications of the particular standards. But the details of the policy only matter if enforcement is even possible. Even government units whose entire job consists of enforcing standards on industry are not very effective at it -- as evident in any news story about foodborne outbreaks or energy industry accidents -- and there is no reason to believe that FDA, with its numerous other priorities, would be able to do better.

The previous paragraph describes the challenges of a real regulation. But it is actually moot for this proposed rule. Long before FDA could develop the expertise to create and enforce manufacturing standards, and perhaps even before they could manage to adopt third-party standards, the grace period for existing products would expire and all that manufacturing would be banned. The only exceptions would be a few hand-picked major manufacturers for whom generic guidelines would be unnecessary because they would be under total control. FDA may have no plans to develop real regulatory standards because they anticipate this outcome, but if that is the case, they should clearly state it rather than implying they can provide useful standards; if they have standards planned, they should specify them.

Thus, the best *theoretical* outcome here for real regulation would be (a) perhaps slightly better monitoring and ability to intervene than currently exists to deal with a problem that has never actually occurred, and (b) the theoretical possibility of developing practice standards that might or might not happen, and even if it did would probably happen faster if industry were allowed to evolve their own practice guidelines. But even these theoretical benefits will not be achieved under the ban. Instead, the actual results of the ban will make manufacturing disasters more likely and harmful and good manufacturing practices less common.

In the alternative markets that will emerge, the illegal and borderline-legal supply chains would be murky and undoubtedly use less reliable manufacturing practices. In contrast with the current situation, authorities could have a rather difficult time finding manufacturers, which would be overseas or underground, if they needed to. Black-market producers and suppliers would be rather less concerned about brand equity or possible repercussions of errors than current manufacturers, and probably less concerned about the health of their customers. Standards would be unenforceable and, indeed, undetectable. Dealers of currently illicit substances obviously have some interest in their reputations and the well-being of their customers, but they are not exactly known for being overly committed to them. DIY manufacturing is unlikely to cause any major

outbreak-type incidents, but it is far more likely to hurt individual consumers at either the production or the consumption stage.

Thus, the *potential* benefits in this area are modest and based entirely on unsubstantiated assertions by FDA rather than any concrete proposals. The reality is the proposed rule would *cause* these problems, not prevent them.

#### Regulating HPHCs and other product standards

Real regulation of e-cigarettes (by anyone) could lead to sensible restrictions on ingredients for e-cigarette liquid, as well as standards for batteries, coil temperatures, and other product characteristics. Once again, this could theoretically be good for consumers and reputable producers, but the specific proposed regulation will undoubtedly do more harm than good.

Consider the easiest e-cigarette components to regulate, batteries and chargers. Very safe versions of these ubiquitous devices are available, which reduce the risk of both hardware problems and operator error, and reputable e-cigarette manufacturers use such products. It is also easy to buy or incorporate into devices shoddy equipment that produces needless levels of risk for fires or other problems (still not a huge risk, but needless), just as it is possible to buy a third-party charger that will incinerate your iPhone. Depending on the details of the proposed regulation and how much latitude the courts grant for interpreting the TCA, FDA might have no authority over these hardware components, making the issue moot. If FDA were able to assert jurisdiction, however, this would result in elimination of the legal market for both the shoddy products and all but a few of the high-quality closed-system products. Under that scenario, the market for open-system batteries would be served entirely by shady alternative markets, almost certainly resulting in a reduction in the average quality of what was sold. Quality could only be assured by individual consumers gaining sufficient expertise to know what to buy.

Other hardware standards are also potentially beneficial if they could be imposed, such as by governing maximum temperatures to reduce hazardous pyrolysis products. Again, there is the reasonable possibility that FDA could not regulate these devices, making the matter moot. If they could, the result would be elimination of the above-ground manufacturers of higher-quality products, almost certainly resulting in a net reduction in average quality. But even setting aside this fatal error in the plan, what standards? FDA has no expertise in this area.

Battery systems are well understood by manufacturers, regulators, and third-parties observers. But knowledge about what characteristics of e-cigarette hardware matter for health and safety is extremely limited. Any such standards imposed in the near future would be largely arbitrary, and there are no obviously beneficial rules that do not merely prevent problems that consumers already choose to avoid (e.g., leaky tanks, extreme overheating). Neither FDA nor the

researchers it funds have shown the interest or the capacity to research how to improve hardware quality. Advancing knowledge about these points comes only from industry. That advance can only be hurt by eliminating most of the responsible manufacturers who can contribute to such efforts.

Reduction of harmful ingredients in e-cigarette liquid is potentially beneficial for consumers and high-quality manufacturers. FDA ostensibly already regulates “hazardous and potentially hazardous constituents” (HPHC) in tobacco products. In reality, the HPHC process exists in name only, and FDA has taken no action in that area regarding the tobacco products it already regulates. What push there is for product standards under the HPHC process appears to be primarily motivated by just making the products more expensive to manufacture or lower quality for consumers, rather than being based on any analysis about what would benefit consumers.

Knowledge about how to avoid needless hazard from e-cigarette liquid is mostly limited to rather obvious restrictions (e.g., do not use lead acetate as a flavoring agent, and it is almost certainly better to stick to ingredients that are approved as food additives). Beyond that, the knowledge base runs fairly thin. Once again, FDA and the researchers it funds have contributed nothing useful to that knowledge base, and it is advanced mainly by industry. Thus, HPHC regulation would be *potentially* beneficial, but there would be no prospect of it actually happening in the short to medium term. It seems likely that any such regulation would start with FDA jumping on the bandwagon to ban the half-dozen flavoring agents that have become controversial, such as diacetyl. The problem with this is that there is not actually very compelling evidence that these are causing harm.

In any case, the apparent inability of FDA to engage in evidence-based regulation on this point is once again moot, because they are proposing a ban, not regulation. Much of the current *de facto* regulation of HPHC ingredients would be lost with the replacement of major reputable producers with a shady supply chain with far less quality control and expertise. The net result would clearly harm the goal of making e-cigarette liquid less hazardous rather than advance it. Hypothetical real regulation might also tend to do some of the same: A ban on a single popular flavoring agent would result in some consumers adding it themselves and/or acquiring products via the black market. FDA’s more likely approach, banning all ingredients other than a short list that are explicitly approved, would create alternative markets almost as effectively as would an out-and-out ban of the products.

Similarly, FDA claimed in their draft regulation that they would be able to intervene in the event of “adulteration and misbranding.” There is no evidence that these occur or cause harm. But even if they did, FDA would have no such ability for the alternative markets, and have never offered

any concrete statements of what they could accomplish in this area before the market was driven underground.

#### Informing consumers and conducting research

Another vaguely cited justification in the draft regulation was to ensure consumers are adequately informed about e-cigarettes. But there is no indication that FDA plans to disseminate any information that only a regulator can produce (e.g., publishing the ingredients of all products that remain in the legal market) and FDA has already joined the general public discussion about e-cigarettes. There is no apparent communication that would be enabled by this rule. If there is, FDA should explicitly indicate what it is, so that its supposed contribution to consumers can be evaluated.

What FDA seems to be claiming is that they would be act to make consumers *less* informed. FDA has already published a draft rule on “intended use” that would (in the unlikely event it were not found to be unconstitutional) prevent manufacturers, merchants, or trade organizations from merely telling consumers that e-cigarettes are intended as a substitute for smoking, let alone tell them it is a low-risk substitute. The effects of such restrictions would clearly be negative. In our comments on that proposed rule,<sup>16</sup> we point out this is harmful, depriving consumers of useful and health-beneficial rules -- particularly the most disadvantaged smokers who often lack social networks and information sources, and thus are more reliant on merchants’ communications to learn about e-cigarettes. Moreover, it will effectively prevent the existing marketing that targets smokers and force industry to engage in untargeted marketing that might appeal more to nonsmokers.

In the draft regulation, FDA claimed defining “would reduce the use of misleading claims on the products to allow for better-informed decision-making by consumers and would prohibit these products from being targeted to youth populations.” But FDA provides *no* evidence that there are any misleading or harmful claims about the products. What FDA has proposed is prohibiting *accurate* and *beneficial* claims about e-cigarettes being a good alternative to smoking. Similarly, there is no evidence that any information targets “youth populations”; FDA has never even suggested what might constitute such targeting. If FDA did actually define their claim and then established it really was a problem, it seems likely that their plan -- forcing merchants to engage in marketing that does not specifically target adult smokers -- would make it worse.

There is no reason to expect FDA could improve the information flow on the topic. Any consumers who really want information have ample authoritative sources for it that they

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<sup>16</sup> See: <http://blog.casaa.org/2015/12/casaa-comment-on-fda-proposed-intended.html>. Note that at the time of this writing, the comment that appears at that link has not yet been submitted, but we expect that our final comment will be nearly identical.

probably trust more than they trust FDA. Given FDA's plan to ban the most beneficial commercial speech and their history with smokeless tobacco, there is reason for serious concern that any smoker who does get their information from FDA will be discouraged from practicing harm reduction. Indeed, this may already be happening. The major misinformation problem that exists currently -- in terms of both prevalence and the harm it causes -- is that many smokers have been convinced by a concerted disinformation campaign that e-cigarette use is just as harmful as smoking. FDA has not suggested they will do anything to try to remedy this situation, and their proposed "intended use" rule would tend to make the problem worse. As with all of their claims of benefits, FDA has failed to present a case for how their action would lead to a particular beneficial outcome, let alone quantify the benefits.

The replacement of the legal market with alternative markets further erodes even the theoretical possibility of benefits. Consumers using the alternative markets would turn to social networks for information, removing all regulatory control. For many this would mean getting far better information, from organizations like CASAA, than they get from government, the media, or manufacturers. For some, though, it could mean that they are getting most of their information from a shady "dealer."

Related to information dissemination is information gathering. FDA claims in the draft regulation, "Deeming these products would permit us to collect information about their ingredients to ensure that other potentially harmful constituents are not present. Deeming would also allow us to collect information regarding health and behavioral effects of these products." But FDA is already doing research and gathering information without regulatory authority. FDA is the dominant funder of non-industry research on e-cigarettes. The only change that regulation would bring is requiring the few approved legal manufacturers to file HPHC statements which, as already noted, provide no operationalizable information. Collecting that information on a handful of products could easily have been done as part of the research FDA is currently funding if they actually believed such data was useful. Thus there is no apparent benefit here. There is, however, an implicit concession that FDA does not have enough knowledge about the health and behavioral effects of e-cigarettes that they should be imposing a massive intervention in the market.

#### Discouraging underage use

FDA is clearly trying to sell this proposal primarily on the basis that it would reduce use of e-cigarettes by minors. FDA, CDC, and other political actors have been deluging the press and public with alarmist claims about underage use to bolster support for the proposed e-cigarette ban. There are three problems with this: (i) underage use is not nearly as great as the rhetoric claims, (ii) there is no reason to believe the proposal would accomplish the goal of reducing such use, and (iii) it is not actually clear it would be beneficial on net if it did.

The alarmist rhetoric about underage use of e-cigarettes is based on surveys that ask minors if they have taken so much as a single puff from an e-cigarette, possibly one that did not even contain nicotine. These are measures of *trying* e-cigarettes. This is then conflated with actually *using* the products by referring to someone who took a single puff in the last 30 days as a “current user” and a single puff ever in her life as someone who “has used” e-cigarettes. What is communicated to the public and policy makers -- undoubtedly intentionally -- is the implication that all these individuals make or made a practice of regularly using these products. (Note that most of the same surveys only categorize someone a current- or ever-smoker if she smoked at least 100 cigarettes, approximately 1000 puffs.)

The reality is that the number of teenagers who are actually *using* e-cigarettes, in any meaningful sense of the term, is quite small. Much of the alarmist rhetoric contains innuendo that we should be terribly concerned with teenagers merely trying a bit of nicotine (and, again, the surveys seldom even determine if the device contained nicotine). But there is no reason for such concern, even setting aside the fact that the rule offers no serious possibility of reducing that trying and that underage use is very likely reducing harms on net.

FDA has highlighted that this proposal would implement a nationwide ban on e-cigarette sales to minors. This is redundant with state-level laws in almost every state, and not selling to minors always been the practice of reputable merchants.<sup>17</sup> Since minors who obtain e-cigarettes now almost always do so personally from legal purchasers or via purchasing, usually illegally from less reputable suppliers, it seems difficult to see why this rule would make any difference.

American minors have little difficulty obtaining cigarettes and alcohol even though all sales to them are banned and, indeed, state laws often also criminalize underage buying as a status offense. Once the e-cigarette market is driven underground, minors will presumably find it even easier to buy from the same suppliers that spring up to supply adults with illegal products. Illegal suppliers tend to not hesitate to sell to any interested customer. It is not difficult for minors to obtain other substances, after all, including many that are illegal to buy, sell, or possess. If a large portion of teenagers who do not circumvent status laws really were using e-cigarettes as a casual practice, *and* if there were not already state sales bans, then *perhaps* the federal sales ban could have its intended effect to some extent. But the reality is that the small percentage of teenagers who are genuinely using e-cigarettes are already doing despite sales bans, and moreover all available research suggests that they are the same teenagers who are using other substances they are not supposed to have access to.

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<sup>17</sup> It is worth noting that the only resistance to state-level bans on sales to minors has come from activists who *oppose* e-cigarettes, and were trying to use the lack of such sales bans as an excuse for imposing draconian regulations like the proposed FDA ban. CASAA, along with the industry, have universally supported state and local bans on sales to minors.

The other step FDA seems likely to take is to ban flavors that are (inaccurately) characterized as “kid friendly.” Rumor is that such a ban is included in the proposed regulation, to take effect well before the grace period expires and all products are banned. Whether or not this is true, FDA has made clear that they are interested in eliminating flavor options (thereby harming adults and reducing smoking cessation, as noted above). But there is *no* evidence that minors are attracted to e-cigarettes due to interesting flavors beyond, perhaps, wanting to sample them once. What evidence there is actually suggests just the opposite,<sup>18</sup> as does common knowledge about teenagers who choose to engage in a forbidden or discouraged activity: They are seeking to behave like adults, not bubblegum-chewing children.

Of course, anything that lowers the quality of a product for some consumers, as eliminating interesting flavors would, will dissuade some marginal consumers from using it, including some minors. But it is an unsubstantiated myth, supported only by repetition rather than evidence, that eliminating product flavoring options will cause any substantial reduction in underage use. In particular, it seems likely that minors most apt to be affected are those who are interested only in trying flavors, rather than making a practice of consuming nicotine, and are thus are not using nicotine-containing liquid in the first place (and so their products of choice might not even be within FDA jurisdiction). Neither FDA nor anyone else has presented even *prima facie* evidence that suggests that eliminating interesting flavors would change the rate of underage e-cigarette use, let alone an analysis of the impact of the particular proposed intervention.

In any case, this move by FDA would *not* eliminate minors’ access to flavored e-cigarettes, and might even increase it. Banning flavors that adult vapers like -- and, as discussed above, there is every indication they like them more than minors do -- would immediately create the alternative supply chains, with their greater ease of underage purchasing. In our survey, 89% of respondents said they would turn to alternative markets under a ban of flavors only, only 2 percentage points lower than the 91% who said they would do so in the event of a total ban. In other words, the rumored flavor ban would merely accelerate the takeover of the market by other channels, not eliminate the availability of those products. Moreover, teenagers are just as capable as adults of DIY flavoring, and every interested teenager will be able to find instructions in minutes. Creating a culture of e-cigarette liquid crafting among high-schoolers seems likely to have exactly opposite the intended effect.

Similarly, there is no reason to believe that the ultimate ban will decrease teenage use or trying of e-cigarettes. Assuming a few cigalike products are allowed through PMTA, teenagers who are interested in trying *some* e-cigarette will still have access to them via the same supply chain they now use. Teenagers who have become enthusiasts of open systems will have access to the same

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<sup>18</sup> <http://ntr.oxfordjournals.org/content/early/2015/01/06/ntr.ntu333.short>

black markets and DIY knowledge that adults have. Even as adult smokers are discouraged from switching by the diminished visibility and convenience of e-cigarettes, teenagers' greater social networking (both online and face-to-face) means that their awareness of and interest in e-cigarettes might remain undiminished. Indeed, the ban might ensure that e-cigarettes do not become seen by teenagers as something millions of boring adults do because they are too lame to quit smoking otherwise (like all children are repeatedly told they should), but rather remain something edgy and rebellious, potentially making them more appealing.

Those latter bits are speculation, of course. But that is the point. The claim that the rule would reduce underage use of e-cigarettes is also pure speculation, backed by no evidence or even a story about how FDA actions would lead to the intended results. There is nothing about the proposal that would substantially reduce access, and there little doubt that black markets will facilitate access by minors.

This begs the question of whether reducing minors' access to e-cigarettes is even a wise goal. It is politically incorrect to suggest otherwise, of course, but since there are reasons it might not be, FDA cannot be excused from analyzing the question. In a world where minors did not smoke or use other drugs, it might go without saying (based on widespread notions of how minor status should limit freedom) that minors should be prevented from using e-cigarettes. But in the real world, e-cigarettes are often a substitute for much more harmful behaviors among minors, just as they almost always are for adults. There is woefully little evidence about this, despite the innuendo that any underage use must be creating harm rather than reducing it. What evidence there is all suggests that e-cigarettes are widely used for THR among teenagers, just as they are among adults. All available data on the point shows e-cigarette use by minors (i.e., not just trying) is overwhelmingly concentrated among smokers, making it plausible they are being used for THR.<sup>19</sup> That association alone is not sufficient to draw that conclusion, of course, but makes it very plausible that interfering with the market would have the same effect it will for adults: more smoking and thus more health risk. In addition, someone who is using e-cigarettes is not -- at least at that very minute -- engaging in an alternative behavior that is potentially even more harmful than smoking a cigarette. We do not know how often that is the case, but this is more reason to ask whether discouraging vaping among teenagers does more good than harm. As noted above, there is no reason whatsoever to believe that e-cigarettes are causing smoking or other harmful behaviors.

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<sup>19</sup> There is disturbingly little real information about U.S. teenagers who have tried/used e-cigarettes, beyond the "have you ever tried one puff?" surveys, despite all the sound and fury. There is better information from the UK, which makes clear that -- just as we would expect -- teens who use e-cigarettes are the same ones who use other substances (e.g., [http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf)).

The goal of discouraging use by minors is presented as if it is self-evidently good. But given that it has obvious potential downsides -- we are not exactly wanting for examples of drug war, anti-harm-reduction, or status offense policies that did more harm than good -- it is incumbent on FDA to provide some support for this claim. After doing that, they need to provide some reason to believe the proposed rule or anything that will follow will actually accomplish that, which does not appear to be the case. They have never done either, let alone tried to quantify the supposed benefits to compare them to the enormous costs.

#### Discouraging harm reduction by adults

A list of the ostensible benefits of banning e-cigarettes cannot be complete without recognizing that many tobacco controllers and temperance-style moralists consider the discouraging of THR to be a feature, not a bug. For reasons we have documented elsewhere,<sup>20</sup> many of those with influence in this area do not support the proposed ban in spite of it causing more people to stay smokers, but in part *because* it would cause that. It is useful to understand this to understand why there is so much support for a proposal that seemingly has no benefits. These activists are not doubting that the predicted reduction in smoking cessation will occur -- they are counting on it. While this is immaterial for analyzing the effects of the rule, it is useful for understanding why anyone would support it despite the lack of apparent benefits.

Needless to say, most people do not share their opinion that discouraging harm reduction is a benefit, and indeed would consider their goal unconscionably unethical if it were recognized. Thus, this goal is never openly stated and such results are never defended as a benefit. In particular, FDA insists that it supports THR and has never suggested that the anti-THR effects of the proposal are a benefit. Thus, for purposes of evaluating the policy, the anti-THR effect should be considered entirely a cost in spite of the fact that a vocal extremist minority might tacitly consider it a benefit.

#### The proposed rule fails a cost-benefit test by default

There is no reason to believe that the proposal will accomplish any of its stated or implicit goals, other than the child-resistant packaging rule whose benefits appear very small and which could easily be achieved by stand-alone legislation that would pass without opposition. Even if the (enormous) costs are ignored, this policy does not seem to pass a cost-benefit test.

Of course FDA could argue that we are wrong about one or more of these assessments of what would really occur under the policy. But they have not done so, ever. The proponents of the policy act as if the stated goal of a specific policy action will be accomplished by that action simply because it is the stated goal.

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<sup>20</sup> <http://antithrlies.com/2015/07/21/why-is-there-anti-thr-1/>

### **Additional departures from good government policy**

While the enormous material social costs of the proposed rule result from attempting to deny consumers a beloved product, discouraging smoking cessation, and creating inferior alternative markets, it is worth highlighting several specific ways in which the rule violates norms of good public policy. Such norms exist for good reason: Violating them is likely to lead to bad outcomes. These problems alone are sufficient reason to send this proposal back to the drawing board.

#### Fundamental misrepresentation of what is being proposed

As already noted, this “regulation” is really a blanket ban (with hand-picked exceptions) and could be largely replaced with a single sentence. Were it presented in terms of that single sentence, it would be rather more apparent to observers that they may not understand what is really happening, though they would not know what. (It would be akin to consequential legislative amendments that consist entirely of single-word changes to referenced lines from the original legislation.) The additional language in the draft version of the regulation, and presumably in the current version, that discusses concerns and goals further obscures the true impact, by implying that the result of the regulation would be specific policies to address these concerns.

Consider a recent news poll<sup>21</sup> that was interpreted as saying most (57%) Americans support the regulation. The subjects were asked, “Do you believe e-cigarettes should be regulated by the FDA like tobacco products?” It seems safe to assume that not one of them understood that the question they were really answering was, “Do you believe that FDA should ban all e-cigarette products, followed by allowing a few major tobacco companies to spend \$20 million per product to request permission to allow a product or two onto the market, applications which FDA would then grant or deny arbitrarily, with the result being less than 20 expensive and low-efficiency products remaining on the market?”

#### Radical intervention, based on ignorance, without consideration of the consequences

The CDC estimated that 9 million American adults had taken at least one puff from an e-cigarette in the last 30 days at the time of a 2014 survey.<sup>22</sup> There are several million regular vapers who are dedicated to the practice. As previously noted, there are probably hundreds of thousands of people for whom e-cigarettes rank in importance behind only basic necessities, friends, and family. This is not some designer drug, where a ban would affect only a handful of people for whom it was only a passing fancy. The impact of the deeming rule is arguable the

<sup>21</sup> <http://www.npr.org/sections/health-shots/2015/10/27/452244929/poll-most-americans-support-fda-regulation-of-e-cigarettes>

<sup>22</sup> <http://www.cdc.gov/nchs/data/databriefs/db217.htm>

second most impactful domestic policy action of the last decade, behind only the Affordable Care Act.

When dealing with a widespread and important social phenomenon, precipitous action is generally unwise, which is why it is seldom attempted. Perhaps it can be justified based on a desperate need for rapid action, but that clearly does not exist in this case (and, indeed, the action has been far from rapid). The only historical examples of restrictive policies that had such sweeping implications are so extreme that it might be taken as hyperbole to even name them.

This sweeping rule is being justified based on very limited understanding of the role of e-cigarettes in people's lives, what will really result from the ban, and even the fundamental biomedical science. As we have previously documented, the draft regulation demonstrated extreme naivety, as did the series of journal articles FDA created simultaneously, the workshops that FDA hosted for purposes of learning about the topic contained almost no accurate information that anyone reasonably expert in the topic did not know already, and the researchers that FDA has funded have produced nothing particularly informative other than chemistry studies. FDA's "we are still getting up to speed" position is perhaps not unreasonable for an agency that is starting to cautiously regulate a product. However, it is a fatal flaw given the sweeping consequences of the deeming.

Radical actions dramatically increase the chance of major unintended/unforeseen/secondary consequences. This alone makes this a bad public policy, even apart from the above analysis that points out what those consequences will be and how they undermine every goal of the policy. Had FDA succeeded in banning e-cigarettes before they became popular, it would have been a relatively conservative policy and it would have been fairly successful. It still would have been extremely harmful on net, but at least it would have accomplished what was intended.

FDA's tobacco regulators seem to be generally unaware that social policies almost always have unintended consequences. Perhaps this is explained by the agency's history regulating pharmaceuticals, where a ruling generally causes exactly the intended results and nothing more. A microcosm of this can be found in FDA's recent draft rules that would forbid e-cigarette manufacturers from even mentioning that the products are a substitute for cigarettes.<sup>23</sup> Setting aside their goal of promulgating a rule that clearly exceeds their legal authority, one obvious implication of this rule would be that manufacturers would be forced into exactly the type of untargeted advertising that FDA and supporters of restrictions most object to.

Thus, even apart from the specific predictable consequences and other problems, FDA is proposing to implement a massive social engineering project as if it were a case of refusing to

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<sup>23</sup> See our comment at <http://blog.casaa.org/2015/12/casaa-comment-on-fda-proposed-intended.html>

approve a new pharmaceutical until more data could be gathered. This observation alone makes it clear this is bad policy.

Failure to analyze how the rule will supposedly create benefits

This was noted many times above in context, but it is worth mentioning as a stand-alone problem. FDA has never explained how their actions will bring about any intended outcome. Our analysis, above, of what will and will not actually occur is not a rebuttal to FDA's contrary claims about what will occur. FDA never actually made any such claims. This alone makes this policy indefensible given that it is a major intervention, not the substance-free assertion of authority it is portrayed to be.

Creation of a legal and enforcement nightmare, and normalizing flouting of laws

All regulations that have a huge impact on industry generate lawsuits, and this will be no exception. Many medium-sized businesses and countless small businesses will face elimination in the face of this regulation, and will undoubtedly sue to prevent its implementation. They will have a strong case. But in the present case, the legal problems will not begin or end there.

The alternative markets will result in laws being violated or circumvented by otherwise law-abiding citizens because they consider them invalid. This alone is harmful to the rule of law. Policing authorities will need to decide whether they are actually going to try to aggressively enforce violations, which is costly and builds resentment, or not, which encourages disdain for the law. The self-import side of the alternative markets will create a similar dilemma and burden for Customs authorities. The black market will tend to enrich the same unsavory sectors of society that are enriched by other black markets. It is impossible to imagine a scenario where the alternative markets do not create major costs even apart from lowering the average quality of e-cigarettes, as discussed above.

There are rumors that FDA will try to ban "flavored" e-cigarette liquid within months after asserting jurisdiction, rather than waiting for the grace period to run out for the universal ban. This seems to be based on a failure to understand that all e-cigarette flavors are created, and thus an e-cigarette is "tobacco flavored" as a result of adding particular flavors that someone thinks make it taste like tobacco. Banning flavored cigarettes is a relatively simple matter of forbidding the addition of any strong flavorings. But if FDA bans the sale of other flavors while "tobacco flavored" liquid is still legal, look for manufacturers to relabel existing products along the lines of "Tobacco A" (which some might say tastes like apple), "Tobacco B" (with "hints" of bubblegum), "Tobacco C" (cherry), etc. FDA will scramble their limited resources to detect and issue cease and desist orders in a few cases, but will be overwhelmed. If anyone fights back against these, it will become apparent that FDA cannot actually define a flavoring sufficiently for

it to be the basis for legal enforcement. The result will be legal battles that will subject the U.S. government to ridicule and flouting of the law that will help pave the way for the black market.

There will also be legal fights around the edge of the black market. FDA has provided mixed signals about whether they will try to extend their jurisdiction beyond nicotine-containing liquids and devices that contain those liquids, to zero-nicotine liquids and modular hardware components, which are rather difficult to call tobacco products under the TCA. If FDA does not extend their reach, legal businesses will continue to thrive on the internet and even in bricks-and-mortar stores, supplying a market that ultimately depends on a black market component (and connecting people with that black or DIY market). Should FDA try to extend their reach, hardware components will be sold as cannabis vaporizers and zero-nicotine liquid will be sold as something (maybe flavoring to be added to carbonated water?). Enforcement authorities will have a very difficult time challenging these claims and will be vulnerable to lawsuits over every enforcement action.

However these play out, it is safe to predict the enforcement process will probably be a greater blow to the government's credibility than cannabis prohibition has been.

#### Delegitimizing FDA and other federal government regulators

As already noted, FDA "regulation" of tobacco products is not real regulation. It is a social activism policy being implemented under the guise of regulation. Consumers of the products are in no way represented in the process (despite explicit requirements that they be represented), and the actions are primarily designed to deprive them of choices rather than benefit them in the way real regulation does. The actions taken do not match FDA's rhetoric. But because of the relatively subtle impacts on the tobacco products currently under FDA jurisdiction, this has not been widely recognized. The e-cigarette ban would change that, creating much wider recognition and hostility. It would reduce trust in federal regulatory processes for millions of e-cigarette consumers and tens of millions of other Americans who understand that this is a harmful and unjustified policy.

#### Creation of health disparities

Reducing disparities in health outcomes by social class or among identifiable subpopulations is often considered worthy of specific public policy attention. But the proposed policy would undoubtedly exacerbate such disparities. People with lower income or less education are far more likely to smoke, and thus suffer the health effects of smoking, as are members of a few identifiable less-empowered subgroups. Restricting access to e-cigarettes would exacerbate the health disparities by causing smokers, who are disproportionately lower socioeconomic status (SES), to keep smoking or return to smoking.

Moreover, the specific impacts of the rule would further exacerbate these disparities. The widespread visibility of e-cigarette suppliers and of advertising can reach lower SES consumers who might not otherwise learn about this low-risk alternative. The post-ban alternative markets will be much more accessible to consumers who are wealthier, more socially connected, and more conversant in information-age commerce. The knowledge that switching to e-cigarettes is wise will still be easily obtainable by more educated people who can distinguish good information from propaganda, but not to the average smoker. (This is similar to the situation with smokeless tobacco now, where a sophisticated consumer can fairly easily figure out it is low risk, but most Americans are tricked into believing otherwise. People who travel internationally will have an easier time self-importing products. Those who can afford the cost of a few Customs seizures will be able to order from overseas. Those who are better connected will find the black market. But the least well-off of smokers will not have those options. In addition, the history of drug wars shows that enforcement tends to be limited to the poor and disempowered sectors of society.

#### Creating a government-sponsored oligopoly

Assuming FDA allows any e-cigarettes through the PMTA process, they will be granted an unassailable oligopoly position in what is now a very competitive market. The costs to consumers from this include increased prices due to oligopoly rents. Incentives to innovate would be reduced (indeed, given how hard it would be to improve a product, getting further FDA approvals, such incentives would be close to nil). There would be little need for the oligopolists to compete on either price or quality.

Moreover, the oligopolists will be chosen and protected by the action of a small cadre of unelected government officials. Government processes are notoriously bad at picking winners compared to free markets. Moreover, given FDA's inherent hostility toward the tobacco products they regulate, it seems like this tendency could be made worse via the intentional picking of products that would be *losers* in the free market.

The alternative scenario to FDA trying to pick winners, probably unsuccessfully, or intentionally picking losers is even worse: crony capitalism. As with most situations where government grants a rent-generating oligopoly in command economies, or the occasional lapses of otherwise free economies, the arbitrary decision process ensures that the competition for the lucrative oligopoly rents will largely be political. For what it is worth, by far the best connected players in the space -- in terms of constantly being in the ear of FDA as well as influence on Capitol Hill -- are the most derided players in the space, the major traditional tobacco companies.

While the reality is that the alternative markets will soften the negative impacts creating an oligopoly within the legal market, the intention of the rule is still to create that oligopoly and FDA has never seriously acknowledged the impact of the alternative markets. And yet FDA has

made no serious effort to estimate the costs to consumers from the oligopoly as compared to the free market *status quo*.

**No incremental changes could cause this rule to have positive net benefits**

Since the payload of this rule comes from merely having this rule, there is no room for avoiding the huge net negative consequences. There are two avenues for improving the situation under the rule that are widely discussed. Either could reduce (though not eliminate) the harms caused by the rule, though neither would change the fact that there are no apparent benefits. Even under such changes, the impact would still be extremely negative.

Changing the grandfather date

Allowing products that existed as of, say, the date of the published rule to stay on the market without PMTA approval would increase the chance e-cigarette consumers could continue to buy their preferred products and help maintain the availability that will lead current smokers to switch to e-cigarettes. It might delay the elimination of the legal market long enough to provide time for rational policy changes. At the very least, it would eliminate a Kafkaesque absurdity from the whole process (“You should have known this was coming back in 2007, before your company or products even existed, and thus should have made sure to have your products on the market by then like the cigarette companies did.”).

Such a change would basically put e-cigarettes on the same footing as smokeless tobacco: Incumbent manufacturers cannot continue to improve their products, and no innovators can enter the market, but so long as incumbents keep the products just the same, they can keep selling them. But as noted above, the treatment of smokeless tobacco under FDA regulation has been deleterious for consumers, honesty, and public health. It would be worse for e-cigarettes since the innovations in smokeless tobacco that FDA has refused to approve have been few, while e-cigarettes are a developing technology with constant innovation.

But as bad as such a “compromise” seems on its face, it is not even so good as it might sound: It is likely that many smaller e-cigarette manufacturers would not be able to demonstrate that a particular product was on the market before a changed grandfather date or would otherwise fail to properly jump through all the other filing hoops. Direct importers of products, which describes most vape shops and online retailers, would be required to act as manufacturers for purposes of these rules. While the major tobacco companies had no problems with these rules, and would similarly be able to take advantage of a change in the grandfather date for e-cigarettes, smaller manufacturers and specialty retailers would still be driven out of business or be required to restrict their product lines. (Some of the smaller traditional tobacco product manufacturers were unable to prove their products were on the market before the 2007 grandfather date, so this is not

mere speculation.) The paperwork costs alone would be an insurmountable burden for many small businesses; these are administrative burdens that are designed for large corporations with huge sales per SKU, not tiny manufacturers whose average revenue from each of their hundreds of SKUs is small.

Many manufacturers and retailers would attempt to comply with the rules, but fail to do so to FDA's satisfaction. They would probably keep selling their products, but technically it would be illegal and eventually subject to FDA enforcement action. Many small manufacturers would just exit the market rather than deal with this exposure. Some would move immediately into the black market. Any manufacturer who made a tiny adjustment in one of their products (say, because a particular flavoring agent or piece of wiring was discontinued by a supplier) would technically need to go through an expensive and usually denied SE application. Chances are that many smaller players would simply ignore this requirement, creating further risk of enforcement action (and enforcement burden for FDA).

Moreover, if FDA was forced to forgo the blanket ban, they would undoubtedly move to impose various specific rules and standards. Any product that did not meet them would have to be changed and then (reintroducing Kafka) have to get permission for the change through the SE process. This application -- even if the manufacturer could afford to make it -- could then be denied arbitrarily. Overt prohibition efforts would also be likely, particularly including banning most flavor profiles. Moreover, innovation would continue outside the legal U.S. market, creating an incentive to seek out, through alternative market channels, the better products that have been developed for legal sale elsewhere. Thus, without further policy changes, the legal market under a later grandfather date will converge to being quite similar to the market under the 2007 date, within only a few years, with little difference other than having more of the 2015-technology cigalikes remaining on the legal market.

In any case, FDA has insisted that there is no room for this sort-of-compromise on the grandfather date. The absolute date is written into the enabling legislation and FDA contends that an executive branch agency cannot change it. They have an arguably reasonable constitutional argument there, which is one of several reasons why we said, in our comments on the draft rule last year, that if FDA really wanted to do what they say they want to do, they would ask Congress for new legislation before acting on e-cigarettes. Indeed, new legislation about regulating all low-risk alternatives to smoking sensibly, rather than bundling them in with a law that is really about discouraging product use rather than regulating, would be the best idea. There is some movement to get Congress to change the e-cigarette grandfather date despite FDA's lack of support for doing so.

But the constitutional issue really seems to be a convenient excuse for FDA given that they cannot really deal with regulating e-cigarettes. There is no indication that FDA is prepared for the enormous increase in their workload that would create. As we discussed at length in our comment on the draft regulation, e-cigarettes are complicated, unlike the tobacco products FDA currently regulates. Even for those much simpler traditional tobacco products, it took FDA half a decade to clear the docket of applications that came in almost immediately upon them being granted authority. Really regulating e-cigarette products will dramatically increase the demands on FDA's tobacco regulators. If the grandfather date were moved, FDA does not even have the capacity to handle the resulting registration paperwork.

#### A clear and reasonable approvals process

For many reasons, FDA should be required to provide a clearly-defined and transparent process for all of the tobacco products they regulate. This is particularly needed if, as they claim, they are not merely imposing arbitrary and insurmountable burdens on low-risk alternatives to smoking. But as noted above, there is no reason to believe they intend to regulate in a manner that would allow most manufacturers to continue to operate.

Before FDA is allowed any additional authority, they should be required to demonstrate they have brought their existing processes into alignment with proper regulatory behavior. The guidances for applications and bases for decisions should be clear. Applicants should be able to assess whether a particular application meets some required standards, and thus will be accepted. Once that is accomplished, the standards then need to be evaluated as to whether they are serving the public and creating net benefit. These are not compromises so much as minimum standards for an agency to be allowed to continue to operate as part of our government.

Once the applications process were made legitimate, it would then be possible to address specific accommodations that would serve the public interest to allow e-cigarettes (and smokeless tobacco) to better compete against cigarettes. These would have to include eased application requirements for low-volume products, the ability to use generic information about the category rather than *de novo* research on the particular product for everything, and favoring applications that contribute to harm reduction. This would be a genuine implementation of FDA's pro-harm-reduction statements.

But it is not really possible to do this within the specific context of the proposed rule. In theory, a rule could include specific process rules that address these problems, though the enormity of the details itself make this unrealistic. Moreover, these processes can only be fixed in practice with no small amount of trial-and-error. FDA has had most of a decade to create legitimate processes and has failed to do so. Until FDA provides a demonstration of proper regulatory process for the products it already regulates, it will be impossible to evaluate the actual ramifications of any

stated process for regulating e-cigarettes, no matter how detailed and promising it might appear. That, of course, is a hypothetical statement, since no details or promising statements have appeared.

Thus a delay in the e-cigarette deeming is required for this fix to have any potential to reduce the huge net harm it will cause.

**Delaying e-cigarette deeming is the only action that can substantially reduce the enormous net harms this rule would cause**

The rule as proposed would do enormous harm to consumer welfare, consumer health, and American businesses, as well as harming the reputation of the U.S. government and the rule of law. It would not accomplish any of its stated goals. The alterations that would be necessary to change any of this are not possible to implement within the bounds of the rule.

Thus, the only good policy option available is to delay FDA deeming of e-cigarettes until such a time that FDA practices and the enabling legislation have changed sufficiently that it can actually create benefit rather than just imposing irreparable harm.

## Appendix - CASAA Survey

This appendix provides a summary of the methods and nature of the CASAA survey whose results appear in the main text. The survey was conducted in November and December of 2015. It was a self-administered online survey that took approximately five to ten minutes to complete. The survey can be viewed, as seen by the subjects, via <https://www.surveymonkey.com/r/Z5ZZCRM> (a flat-file description of the full survey will be created shortly). Subjects were asked slightly different questions depending on their smoking history.

The target population was adults living in the United States who are CASAA members; CASAA membership was approximately 120,000 at the time of the survey. We were able to directly contact approximately 77,000 members by email (the others did not opt in for receiving emails from CASAA) to invite them to participate. An initial invitation and several reminders were sent via email. CASAA members who did not receive the email could take the survey, but would need to find out about it via invitations on our social media accounts or website.

There were 18,398 respondents who received the email and 2,056 others who CASAA members who did not (based on self-report). Of those, 259 indicated they had never been e-cigarette users (defined based on having spent a minimum of \$100 on e-cigarette products for personal use), and are also excluded (the CASAA membership includes users of other smoke-free products and interested non-users; they were also asked to take the survey, though presumably many of them did not bother because they knew it was about e-cigarettes). An additional 5,416 respondents indicated they were not CASAA members and are excluded from this analysis to better define the survey population. Invitations and the survey introduction made clear who the target population was and questions were asked to confirm that status, but respondents who were not in the target population were allowed to complete the survey to minimize the chance someone would misrepresent their status in order to be able to complete the survey.

Because this survey targeted the CASAA membership, it is the best-defined population of any survey of e-cigarette users to date, other than a few population representative surveys that have asked only a couple of questions about e-cigarette use. Previous surveys lacked clearly-defined target populations; they recruited respondents via untargeted social media snowballing, and thus collected a convenience sample of responses from across jurisdictions, whoever happened to be enthusiastic about doing the survey. The e-cigarette users who are CASAA members are a better defined population. They are 99% American. They are clearly not representative of all U.S. e-cigarette users, given that they self-selected to participate in CASAA Calls to Action (advocacy

alerts) or were otherwise interested in joining the organization. They are probably representative of Americans who will be most affected by policy action targeted at e-cigarettes and are sufficiently socially and politically connected to be aware of such actions. The response rate was far higher, as a portion of the target population, than any previous e-cigarette survey, though it was still low enough that there was presumably selection based on enthusiasm within the CASAA population.

We believe the results are reasonably representative of the 1 to 2 million who are actively enthusiastic about e-cigarettes, though some results will represent the perhaps 5 million other e-cigarette users in the USA. In particular, the percentage who achieved particular levels of smoking cessation are clearly not representative of all e-cigarette users (most of the survey respondents quit smoking entirely using e-cigarettes, while most American e-cigarette users have only used them to substitute for some, but not all, of their smoking). However, within the subpopulation who quit entirely using e-cigarettes or merely cut down, the responses are probably reasonably representative. The responses to the questions about planned actions in the event of bans are probably only representative of the enthusiast population, given that plans to seek alternative markets requires knowledge and social connections in the e-cigarette space.

Various results from the study appear in the main text in their relevant context. We are aware that OIRA has indicated an interest in healthcare providers offering advice about e-cigarettes. Our survey produced the following results for CASAA members on that point (answers were not mutually exclusive, and subjects were asked to indicate all that they experienced): 35% reported never talking to a healthcare provider about e-cigarettes; 7% became interested in e-cigarettes in the first place because of something a provider said, and another 6% had received a spontaneous recommendation though they were already using e-cigarettes; 44% were encouraged to use e-cigarettes (usually when they volunteered they were already doing it), but 4% were discouraged from continuing, with 17% getting neutral advice; 23% had been told by a healthcare provider that e-cigarettes pose low risk, and 2% were told they pose high risk.